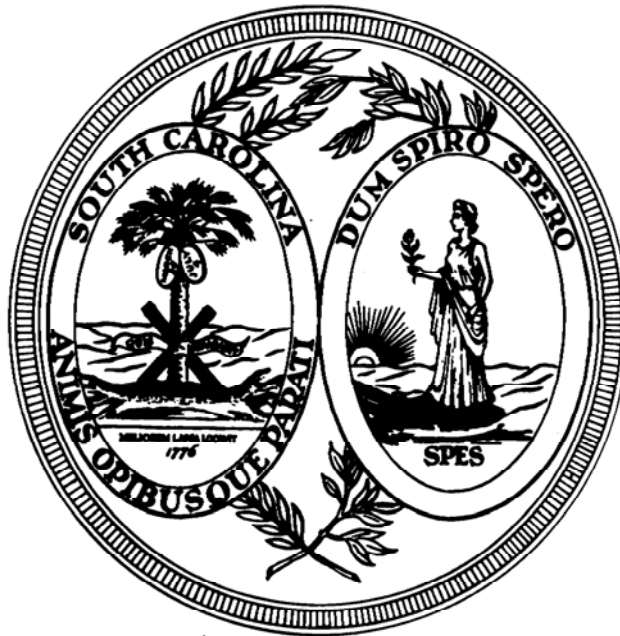




South Carolina Department of Health
and Environmental Control

Regulation Number 61-16

Minimum Standards for Licensing Hospitals and Institutional General Infirmaries



Promulgated by the Board of Health and Environmental Control

Administered by the Division of Health Licensing

Including Changes

Published in the *State Register*, Volume 16, Issue 4, April 24, 1992

Published in the *State Register*, Volume 26, Issue 4, April 26, 2002

This is a courtesy copy of Regulation R61-16

The official document is on record in the *State Register* and the S.C. Code Ann. (2002). This regulation is provided by DHEC for the convenience of the public. Every effort has been made to ensure its accuracy; however, it is not the official text. DHEC reserves the right to withdraw or correct this text if deviations from the official text as published in the *State Register* are found.

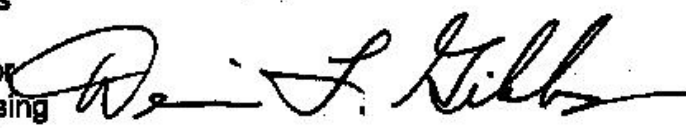
**This copy was updated to correct or note typographical errors between
the *State Register* and the contents of this regulation on December 5, 2003.**



June 16, 2005

MEMORANDUM

TO: Administrators, Hospitals

FROM: Dennis L. Gibbs, Director
Division of Health Licensing 

SUBJ: Lewis Blackman Hospital Patient Safety Act

Compliance with the Lewis Blackman Hospital Patient Safety Act in conjunction with the current standards is required and the Department will enforce the act through inspection.

Article 27, Section 44-7-3410 *et. seq.*, (Lewis Blackman Hospital Patient Safety Act) has been added to the SC Code of Laws, effective June 8, 2005. The Act authorizes DHEC to implement and enforce the provisions contained therein and generally requires hospitals to, among other things:

A. **Identify** all clinical staff, clinical trainees, medical students, interns, and resident physicians (as defined in the Act) as such with identification badges that include their names, their departments, and their job or trainee titles. All the above must be clearly visible and explicitly identified as such on their badges and must be stated in terms or abbreviations reasonably understandable;

B. **Institute** a procedure whereby a patient may request that a nurse call his or her attending physician (as defined in the Act) regarding the patient's personal medical care. If so requested, the nurse shall place the call and notify the physician and or his or her designee of the patient's concerns. If the patient is able to communicate with and desires to call his or her attending physician or designee (as defined in the Act), upon the patient's request, the nurse must provide the patient with the telephone number and assist the patient in placing the call;

C. **Provide** a mechanism available at all times, and the method for accessing it, through which a patient may access prompt assistance for the resolution of the patient's personal medical care concerns. 'Mechanism' means telephone number, beeper

number, or other means of allowing a patient to independently access the patient assistance system. If a patient needs assistance, a clinical staff member or clinical trainee (as defined in the Act) must assist the patient in accessing the mechanism;

D. **Establish** procedures for the implementation of the mechanism providing for initiation of contact with administrative or supervisory clinical staff who shall promptly assess the urgent patient care concern and cause the patient care concern to be addressed;

E. **Provide** to each patient prior to, or at the time of the patient's admission to the hospital for inpatient care or outpatient surgery, written information describing the general role of clinical trainees, medical students, interns, and resident physicians in patient care. This information must also:

1. **State** whether medical students, interns, or resident physicians may be participating in a patient's care, may be making treatment decisions for the patient, or may be participating in or performing, in whole or in part, any surgery on the patient;

2. **Notify** the patient that the attending physician is the person responsible for the patient's care while the patient is in the hospital and that the patient's attending physician may change during the patient's hospitalization;

3. **Include** a description of the mechanism (see above) providing for initiation of contact with administrative or supervisory clinical staff and the method for accessing it.

This memorandum serves only as a general summary of the requirements of the Act. For more specific information concerning The Lewis Blackman Hospital Patient Safety Act, please refer to:

http://www.scstatehouse.net/sess116_2005-2006/bills/3832.htm or the

Department's Health Regulation Home Page:

<http://www.scdhec.gov/hr/>

Should you have any questions regarding this change, please call Randy Clark at (803) 545-4230.

cc: Jim Walker, SC Hospital Association
Karen Price, DHEC
Mary Jo Rou  , DHEC
Jerry L. Paul, DHEC

Leon B. Frishman, DHEC
Jessica J. O. King, DHEC
Nancy Layman, DHEC

Be it enacted by the General Assembly of the State of South Carolina:

"Lewis Blackman Hospital Patient Safety Act"

SECTION 1. Chapter 7, Title 44 of the 1976 Code is amended by adding:

"Article 27
Hospital Patient Safety Act

Section 44-7-3410. This article may be cited as the 'Lewis Blackman Hospital Patient Safety Act'.

Section 44-7-3420. For purposes of this article:

(1) 'Clinical staff' means persons who work in a hospital whose duties include the personal care or medical treatment of patients. 'Clinical staff' includes, but is not limited to, credentialed physicians, physicians' assistants, nurses, nursing aides, medical technicians, therapists, and other individuals involved in the personal care or medical treatment of patients.

(2) 'Clinical trainees' means persons who are receiving health care professional training in a hospital, either paid or unpaid, students or licensed professionals, whose training includes the personal care or medical treatment of patients. 'Clinical trainees' includes, but is not limited to, resident physicians, medical students, nursing students, and other students and individuals in health care professional training in a hospital.

(3) 'Credentialed caregiver' means a nurse practitioner or physician's assistant who is licensed to care for patients within his or her scope of practice.

(4) 'Credentialed physician' means a licensed physician who has completed his or her postgraduate medical training who has medical staff privileges at a hospital.

(5) 'Attending physician' means a licensed physician who has completed his or her postgraduate medical training and who has medical staff privileges at a hospital and who has primary responsibility for a patient's care while the patient is in the hospital.

(6) 'Designee' means a credentialed physician or a credentialed caregiver whom a patient's attending physician has designated to care for the patient in the absence of the attending physician.

(7) 'Medical student' means an individual enrolled in a program culminating in a degree in medicine.

(8) 'Patient' means an individual who is being treated by a physician in a hospital and includes a patient's representative or an individual allowed by law to make health care decisions for a patient who is a minor or who is unable to consent to health care treatment for himself or herself, or both.

(9) 'Resident physician' means an individual who is participating in any graduate medical education program and whose relationship to the patient is under the auspices of the medical education program.

(10) 'Intern' means an individual who is an advanced student or graduate in medicine gaining supervised practical experience.

Section 44-7-3430. All clinical staff, clinical trainees, medical students, interns, and resident physicians of a hospital shall wear badges clearly stating their names, their departments, and their job or trainee titles. All clinical trainees, medical students, interns, and resident physicians must be explicitly identified as such on their badges. This information must be clearly visible and must be stated in terms or abbreviations reasonably understandable to the average person, as recognized by the Department of Health and Environmental Control.

Section 44-7-3440. Except in emergency admissions, a hospital shall provide to each patient prior to, or at the time of the patient's admission to the hospital for inpatient care or outpatient surgery, written information describing the general role of clinical trainees, medical students, interns, and resident physicians in patient care. The written information must also notify the patient that the attending physician is the person

responsible for the patient's care while the patient is in the hospital and that the patient's attending physician may change during the patient's hospitalization depending on the type of care or services required for the patient. The written information must also contain the information described in Section 44-7-3450. The written material must also state generally whether medical students, interns, or resident physicians may be participating in a patient's care, may be making treatment decisions for the patient, or may be participating in or performing, in whole or in part, any surgery on the patient. This document must be separate from the general consent for treatment.

Section 44-7-3450. (A) If at any time a patient requests that a nurse call his or her attending physician regarding the patient's personal medical care, the nurse shall place a call to the attending physician or his or her designee to inform him or her of the patient's concern. If the patient is able to communicate with and desires to call his or her attending physician or designee, upon the patient's request, the nurse must provide the patient with the telephone number and assist the patient in placing the call. A nurse or other clinical staff to whom such a request is made or who receives multiple requests may notify his or her immediate supervisor for assistance.

(B) Each hospital must provide a mechanism, available at all times, through which a patient may access prompt assistance for the resolution of the patient's personal medical care concerns.

For purposes of this section, 'mechanism' means a telephone number, beeper number, or other means of allowing a patient to independently access the patient assistance system and must not be construed as requiring a patient to request information or assistance in order to access the system; however, a clinical staff member or clinical trainee must promptly access the system on behalf of a patient if a patient requests such assistance. A description of this mechanism and the method for accessing it must be included in the written material described in Section 44-7-3440.

(C) The hospital must establish procedures for the implementation of the mechanism, providing for initiation of contact with administrative or supervisory clinical staff who

shall promptly assess, or cause to be assessed, the urgent patient care concern and cause the patient care concern to be addressed.

Section 44-7-3455. The provisions of this article do not apply to hospitals owned or operated by the Department of Mental Health.

Section 44-7-3460. The Department of Health and Environmental Control shall administer and enforce the provisions of this article in accordance with procedures and penalties provided in law and regulation.

Section 44-7-3470. This article does not create a civil cause of action; however, this article must not be construed to preclude a claim that may have otherwise been asserted under common law or any other provision of law."

**STATE OF SOUTH CAROLINA
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
EMERGENCY ORDER**

WHEREAS, hospitals, nursing homes, and other residential care facilities subject to regulation pursuant to SC Code Ann. §44-7-20 *et seq.* and regulations promulgated pursuant thereto are required to prepare and maintain Emergency Evacuation Plans; and

WHEREAS healthcare facility plans must make adequate provisions for:

- (1) Coordinating with sheltering facilities that will receive patients from evacuation areas, so that sheltering facilities named in evacuation plans are aware of that designation and prepared to receive additional patients;
- (2) Demonstrating the capability for transporting residents and patients to sheltering facilities;
- (3) Planning for relocating staff or providing staff at the sheltering facilities;

WHEREAS there is a substantial potential that one or more hurricanes will threaten the South Carolina coast during a hurricane season; and

WHEREAS the identified deficiencies in facility evacuation plans must be corrected promptly;

NOW THEREFORE,

IT IS ORDERED, pursuant to SC Code Ann. §44-1-140 that, in addition to the requirements of Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 207; Regulation 61-17, Standards for Licensing Nursing homes, Section B.8.; Regulation 61-84, Standards for Licensing Community Residential Care Facilities, Section 1401; Regulation 61-13, Standards for Licensing Habilitation Centers for the Mentally Retarded or Persons with Related Conditions, Section B.(8); and Regulation 61-103, Standards for Licensing Residential Treatment Facilities for Children and Adolescents, Section J.6.a.; Regulation 61-78, Standards for Licensing Hospices, Section 1701; and Regulation 61-93, Standards for Licensing Facilities that Treat Individuals for Psychoactive Substance Abuse or Dependence, Section 1502, each facility subject to one or more of the foregoing regulations shall prepare an Emergency Evacuation Plan that conforms to the following requirements:

- (1) (a) A Sheltering Plan for an alternate location to house patients or residents. This Plan shall include: full provision for at least the number of licensed resident or patients beds at that facility; the name, address and phone number of the Sheltering Facility (or Facilities) to which the patients or residents will be relocated during an emergency; a Letter of Agreement signed by an authorized representative of each Sheltering Facility which must include: the number of relocated patients or residents that can be accommodated; sleeping, feeding and medication plans for the relocated patients or residents; and provisions for accommodating relocated staff. The Letter of Agreement must be updated annually and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper and Georgetown Counties, at least one Sheltering Facility must be located in a county other than the six named counties.

(b) In the event a hospital or nursing home is located in an area subject to an order of evacuation and current data from the Army Corps of Engineers indicates the facility will not be affected by the storm surge, the following information must be current and on file with the Department before the facility can be considered for exemption from the mandatory evacuation order:

- (i) A **Critical Data Sheet** must be complete and on file with the Department of Health and Environmental Control which certifies the following:
 - Emergency power supply is available for a minimum of 72 hours;
 - A 72 hour medical supply is available on site;
 - A 72 hour supply of food and water is on site.

The **Critical Data Sheet** website for entering information is located at <http://scangis.dhec.sc.gov/cdatasheet/login.aspx>


- (ii) Adequate staff must be available and on duty to provide continual care for the residents
 - (iii) An engineer's report concerning the wind load the facility should withstand must be on file with the Department;
 - (iv) The facility must request an exemption from the evacuation order from DHEC's Health Licensing Division.
- (2) A Transportation Plan for relocating the patients or residents. The Transportation Plan must include the number and type of vehicles required; how and when they will be obtained; who (by name or organization) will provide drivers; procedures for providing medical support and medications during relocation; the estimated time to accomplish the relocation; and the primary and secondary route to be taken to the sheltering Facility.
- (3) A Staffing Plan for the relocated patients or residents. The Staffing Plan must outline in detail how care will be provided to the relocated patients or residents, including the number and type of staff. If staffing will be provided by the Sheltering Facility, the Staffing Plan must be co-signed by an authorized representative of the Sheltering Facility. If staffing will be provided by the relocating facility, plans for relocating staff or assuring transportation to the Sheltering Facility (Facilities) must be provided.

IT IS FURTHER ORDERED that each facility shall communicate and coordinate with local Emergency Preparedness Divisions in the development and implementation of the Emergency Evacuation Plans.

IT IS FURTHER ORDERED each facility shall certify to DHEC no later than June 1 of each year that the Emergency Evacuation Plan contains a Sheltering Plan, Transportation Plan, and Staffing Plan complying with the terms of this Order, and shall submit to DHEC the name(s) of the Sheltering Facility (Facilities). A copy of this Order shall be provided to each facility.

AND IT IS SO ORDERED.

8-30-04
Date


C. Earl Hunter
Commissioner



DIVISION OF HEALTH LICENSING REGULATIONS

Provider-Wide Exceptions


In the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the patients, residents, and participants cared for in South Carolina licensed facilities, it has been determined that alternative standards will be considered as acceptable. A Provider-Wide Exception (PWE) is the tool that is used to achieve a working relationship between the facility and their regulators. This section may also contain Position Statements that give guidance or interpretations of the regulation.

Note: Some Provider-Wide Exceptions pre-date the publishing dates of specific Regulations established by the *State Register* and may no longer be in effect. In these instances, if there is a conflict between a PWE that pre-dates the publishing date of the regulation, the standard in the regulation shall supercede the PWE.

December 21, 1994

MEMORANDUM

TO: Hospital Administrators

FROM: 
Alan Samuels, Director
Division of Health Licensing

SUBJECT: Conditions that will allow a provider-wide partial exception to the requirements of Section 601.6 (orders for medication and treatment) of Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries.

Section 601.6 of R61-16 requires: "All medical records shall contain the orders for medication and treatment written in ink and signed by the prescriber or his designee. All orders, including verbal orders, shall be properly recorded in the medical record and dated and signed by the prescriber or designee within 48 hours."

Hospitals have experienced difficulty in meeting R61-16, Section 601.6 standards. We also recognize that applying this requirement categorically may interfere with other functions more directly related to quality patient care. In the interest of establishing reasonable standards which can be met by providers and yet do not compromise the health and welfare of patients cared for in South Carolina hospitals we have determined that an alternative standard will be considered as acceptable.

All hospitals will be required to meet either the standard outlined in Regulation 61-16, Section 601.6 or, as an alternative:

A. The hospital's medical staff shall identify and list categories of diagnostic or therapeutic verbal orders (associated with any potential hazard to the patient) that must be authenticated by the prescriber. A copy of this list shall be maintained at each nurses' station.

B. Schedule II controlled substances must be included on the list of drugs which shall be authenticated by the prescriber.

Memo to Hospital Administrators
December 21, 1994
Page 2

C. Verbal orders designated by the medical staff as requiring authentication shall be countersigned and dated by the prescriber or designee within a time frame defined in hospital policy, but in no case more than two (2) days after the order was given.

D. All other R61-16 standards shall apply unless specifically excepted.

This standard in Section 601.6 will be enforced during inspections, as required either by the regulation or the exception.

Please also refer to R61-16, Section 404.3A. for standards on the subject of who may give orders for patient care. Standards on who may receive verbal orders are found in R61-16, Section 404.3B., "Verbal and telephone orders shall be given only to a licensed nurse and immediately recorded, dated and signed. This restriction shall not be construed to prohibit the issuance and acceptance of verbal orders in other specialized departments or services as authorized in the medical staff by-laws, e.g., orders pertaining to respiratory therapy modalities and medications administered therewith may be given to respiratory personnel, radiology instructions to radiology technicians, and physical therapy orders to physical therapists..."

If there are any questions, you may call (803) 737-7202.

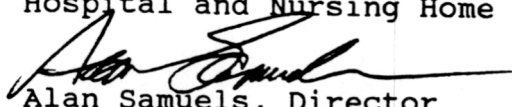
AS/DLG/ms

cc: Doug Bryant, Commissioner
Alice Truluck
William Yates
Karen Reeves

May 5, 1995

MEMORANDUM

TO: Hospital and Nursing Home Administrators

FROM: 
Alan Samuels, Director
Division of Health Licensing

SUBJECT: Conditions that will allow a provider-wide partial exception to the requirements of Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 1005.2, and Regulation 61-17, Standards for Licensing Nursing Homes, Section J.(4)(b)(2).

R61-16, Section 1005.2, requires that, "All linen from patients with infectious or communicable diseases shall be placed in durable bags identified 'contaminated' and transported in these closed bags to the soiled linen holding area or laundry." R61-17, Section J.(4)(b)(2), requires that, "All linen, restraints and resident clothes from residents with infectious or communicable diseases shall be placed in durable bags identified 'Contaminated' and transported in these closed bags to the soiled linen holding area or laundry."

After careful review of the OSHA document Occupational Exposure to Bloodborne Pathogens, 29 CFR Part 1910.1030, published in the Federal Register on December 6, 1991, and in the interest of establishing reasonable standards which can be met by providers and yet do not compromise the health and welfare of patients cared for in South Carolina hospitals or of residents cared for in South Carolina nursing homes, we have determined that an alternative standard will be considered as acceptable.

All hospitals and nursing homes will be required to meet the standard outlined in their respective licensing standard, R61-16 Section 1005.2, or R61-17, Section J.(4)(b)(2), or, as an alternative:

When a facility utilizes Universal Precautions in the handling of all soiled linen, alternative labeling or color-coding of bagged soiled linen is sufficient if it permits all on-site or off-site handlers to recognize the containers as requiring compliance with Universal Precautions. Examples of alternative labeling or color-coding might include, containers labeled, "UNIVERSAL PRECAUTIONS" or red soiled linen bags.

MEMO TO ADMINISTRATORS

May 5, 1995

Page 2

This standard in R61-16, Section 1005.2 or R61-17, J.(4)(b)(2), will be enforced during inspections, as required either by the regulation or the provider-wide exception. This exception applies to any hospital or nursing home licensed by the Department. It relates solely to South Carolina licensing standards. Any adverse condition(s) that may be related to this exception may result in revocation of the exception by the Department.

If there are any questions, you may call (803) 737-7202.


AS:DG

cc: Douglas E. Bryant
Alice Truluck
Robert Ball, M.D.
J. Randall Lee, SCHCA
Elaine E. Guyton, SCANPHA
Louetta A. Slice, SCNHA
William Yates, SCHA

January 13, 1995

MEMORANDUM

TO: Hospital Administrators

FROM: 
Alan Samuels, Director
Division of Health Licensing

SUBJECT: Conditions which will allow provider-wide partial exceptions to the requirements of Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Sections 303. and 605.2.

R61-16, Section 303., requires that, "The medical staff, either as a whole or on a department or clinical service basis, shall meet at least once each month to review and analyze their clinical experience..." We have determined that an alternative standard will be acceptable. All hospitals will be required to meet either the standard outlined in R61-16, Section 303., or as alternative:

The medical staff whether as a whole or on a department or clinical service basis, shall meet at least once every three months to review and analyze their clinical experience. Written minutes of medical staff meetings shall be maintained. The approach for scheduling medical staff meetings shall be outlined in hospital policies and procedures. Quality assurance must be an ongoing process, thus, procedures shall include a stipulation for meeting more frequently when such a need arises.

R61-16, Sections 605.2 and 605.2.2., require that, "There shall be written policies and procedures for the decontamination and sterilization activities...These policies and procedures shall relate, but are not limited to the following:...Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use..." R61-16, Section 605.5, requires that, "...Labels shall include at least the expiration date of the contents."

Page 2
MEMORANDUM
January 13, 1995

We have determined that the "event-related" methodology for determining sterile integrity of hospital-sterilized medical items is a generally accepted professional practice and an acceptable alternative to the "time related" methods outlined in current R61-16 standards. If a hospital desires to implement event related methods for determining shelf life of hospital-sterilized medical items then policies and procedures shall so indicate.

AS:DG:ms


cc: Douglas E. Bryant, Commissioner
Alice Truluck, Customer Service Liaison

March 7, 1995

MEMORANDUM

TO: Hospital Administrators

FROM: John T. McNeely, Deputy Commissioner
Health Regulation



SUBJECT: Consolidation of hospital licenses where separate and
distinct buildings are involved

In certain circumstances there are significant financial incentives and other advantages in the consolidation of multiple hospital buildings under one license. In light of many recent requests from the hospital provider community to consolidate certain hospitals under one license (which hospitals had previously been licensed separately or where one of the units is new construction) and in order to clarify our position on this subject, the following guidelines for when consolidation will be permitted are established:

1. The licensee of the individual facilities must be identical.
2. The facilities must be located on the same premises (or campus.) In order to be considered as "on the same premises" structures must be located on contiguous or adjoining property. Unlimited access roads and/or local streets will not be considered as dividing otherwise adjoining property.

This policy will not affect the licensure of existing hospitals as they are currently licensed, but will be applied whenever future licensure changes are requested.

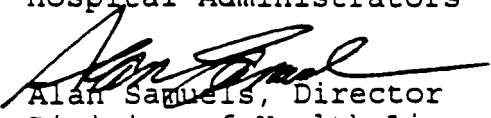
JTM

cc: Douglas E. Bryant
Alice Truluck
Bill Yates, SC Hospital Association

March 7, 1995

MEMORANDUM

TO: Hospital Administrators

FROM: 
Alan Saguels, Director
Division of Health Licensing

SUBJECT: Conditions which will allow provider-wide partial exceptions to the requirements of Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 601.5.

1. Section 601.5.A., requires that "...A minimum medical record shall include the following information:

1. Admission Record: An admission record must be prepared for each patient and must contain the following information, when obtainable: ..."

We have determined that an alternative standard will be acceptable. All hospitals providing obstetric services will be required to meet either the standard outlined in R61-16, Section 601.5.A., or as alternative:

"...A minimum medical record shall include the following information:

1. Admission Record: An admission record must be prepared for each patient except newborns and must contain the following information, when obtainable: ..."

2. Section 601.5.B., outlines the requirements for minimum content of the newborn medical record. We have determined that an alternative standard will be acceptable, and this alternative is indicated by underlining in the following text:

B. Newborn Records:

1. Contingent upon the availability of pertinent information in the prenatal records of the mother, newborn records shall include the following:

a. History of hereditary conditions in mother's and/or father's family;

b. First day of the last menstrual period (L.M.P.) and estimated day of confinement (E.D.C.);

NEWBORN RECORDS MEMORANDUM

March 7, 1995

Page 2

- c. Mother's blood group and RH type -- evidence of sensitization and/or immunization (such as, administration of anti-D hyperimmune globulin);
- d. Serological test for syphilis (including dates performed);
- e. Number, duration and outcome of previous pregnancies, with dates;
- f. Maternal disease (e.g., diabetes, hypertension, pre-eclampsia, infections);
- g. Drugs taken during pregnancy;
- h. Results of measurements of fetal maturity and well-being (e.g., lung maturity and ultrasonography);
- 2. All newborn records shall include the following:
 - a. Drugs administered during labor and delivery;
 - b. Duration of ruptured membranes and labor, including length of second stage;
 - c. Method of delivery, including indications for operative or instrumental interference;
 - d. Complications of labor and delivery (e.g., hemorrhage or evidence of fetal distress), including a representative strip of the fetal ECG if recorded;
 - e. Description of placenta at delivery, including number of umbilical vessels;
 - f. Estimated amount and description of amniotic fluid;
 - g. Apgar scores at 1 and 5 minutes of age. Description of resuscitations, if required, detailed description of abnormalities and problems occurring from birth until transfer to the special care nursery or the referral facility;
 - h. Test results and date specimen was collected for PKU and other metabolic screening tests, in accordance with R61-80, Neonatal Screening for Inborn Metabolic Errors and Hemoglobinopathies. (Exempt only when parents object because of religious convictions; then file copy of executed "Statement of Religious Objection Form, DHEC #1804, with newborn record.)

AS:RB


cc: Douglas E. Bryant
Alice Truluck

Karen Reeves
Elin Holgren

May 20, 1996

MEMORANDUM

TO: Intermediate Care Facility for the Mentally Retarded, Hospital, Nursing Home, and Community Residential Care Facility Administrators

FROM: Alan Samuels, Director
Division of Health Licensing 

SUBJECT: Conditions that will allow a provider-wide partial exception to the requirements of Regulation 61-13, Standards for Licensing Habilitation Centers for the Mentally Retarded or Persons with Related Conditions, Section C.(2)(a); Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 404.1; Regulation 61-17, Standards for Licensing Nursing Homes, Section C.(2)(a); and Regulation 61-84, Standards for Licensing Community Residential Care Facilities, Section 302.

Standards outlined in Regulation 61-13, Section C.(2)(a); Regulation 61-16, Section 404.1; Regulation 61-17, Section C.(2)(a); and Regulation 61-84, Section 302., require that facility policies and procedures be reviewed at least annually. During inspections we have routinely checked for documentation which showed that this was done.

In the interest of establishing reasonable standards which do not compromise the health and welfare of residents/patients living in or receiving care in intermediate care facilities for the mentally retarded, hospitals, nursing homes, and community residential care facilities, we have determined that an alternative standard will be allowed.

All intermediate care facilities for the mentally retarded, hospitals, nursing homes, and community residential care facilities, must meet either the standards outlined in their respective licensing standard, **OR**, as an alternative:

Procedures shall be revised as required in order to reflect actual facility practice. Additionally, facilities shall establish a time frame for overall review of all procedures. This time frame shall be documented in facility procedure and overall reviews shall be documented.

MEMO ADMINISTRATORS

May 20, 1996

Page 2

Facility staff shall work together with the appropriate governing body, management, medical staff, and clinical and managerial leaders in developing, reviewing, and revising procedures as needed. This exception does not change any other standards not specifically addressed in this letter.

The standards in Regulation 61-13, Section C.(2)(a); Regulation 61-16, Section 404.1; Regulation 61-17, Section C.(2)(a); and Regulation 61-84, Section 302., will be enforced during inspections, as required either by the regulation or the provider-wide exception. This exception applies to any intermediate care facility for the mentally retarded, hospital, nursing home, or community residential care facility licensed by the Department. It relates solely to South Carolina licensing standards. Any adverse condition(s) that may be related to this exception may result in revocation of the exception by the Department.

If there are any questions, you may call (803) 737-7202.

AS:DG:dg

cc: Alice Truhuck, SCDHEC
Jim Kirby, SCDDSN
William Yates, SCHA
Christy Buchanan, SCARCH

Elaine E. Guyton, SCANPHA
J. Randall Lee, SCHCA
Louetta A. Slice, SCNHA

November 15, 1996

MEMORANDUM

To: Administrators of Licensed Hospitals, Nursing Homes, Intermediate Care Facilities for the Mentally Retarded, Community Residential Care Facilities, Ambulatory Surgical Facilities, Residential Treatment Facilities for Children and Adolescents, Outpatient Facilities for Chemically Dependent or Addicted Persons, Day Care Facilities for Adults and Renal Dialysis Facilities

Alan Samuels, Director
Division of Health Licensing



Reportable Accidents/Incidents which must be reported to Health Licensing

Licensing standards for your facility require you to notify this division in the event of certain accidents and incidents in your facility that are identified on the attachment to this memorandum. Reporting requirements for each facility vary. Despite these differences, we have established a data base to manage the information that has been submitted.

Our Assessment Program is charged with identifying and reviewing trends which impact the licensing of health and other care facilities and programs. At this time, emphasis is being given to the review of reportable accidents and incidents. Upon study of the information maintained in this data base, we anticipate being able to identify trends facilities and programs are currently experiencing. Upon trend identification, we plan to formulate specific courses of action. Those actions might include regulation amendment, promotion of educational opportunities, and to work in partnership with specific facilities regarding quality assurance programs. We are requesting your assistance with compilation of this data. Please review the current format that you are using to report incidents and accidents to insure it provides the following information:

Facility/Program Name	Extent/Type of Injury and How Treated, e.g. hospitalization
Client Age and Sex;	Identified Cause of Incident/Accident
Date of Incident/Accident/Location	Internal Investigation Results if Cause Unknown
Witness Names	Identity of Other Agencies Notified of Incident
	Date of the Report

The attached form for reporting incident reports is provided as a model. Use of this form is at your discretion. It is not intended to replace the form you are using to record incidents. **Regardless of the format you use, please insure that it includes the above noted information.**

ACCIDENT/INCIDENT REPORT
(Attach additional pages if necessary to provide full report)

Facility/Program Name: _____
Client Age: _____ Sex: _____ Date and Time of the Incident: _____
Specific location of the incident: _____
Describe time of last observation and resident condition: _____

Incident witnessed by staff _____ other clients _____ visitors _____
Names of Witnesses: _____
Describe the incident and injury: _____

Describe client and witness statements that assisted in determining the cause of the incident: _____

What caused the incident? If undetermined, summarize action to determine cause and investigative conclusions: _____

At the time of this report the investigation has not been concluded. Investigative results will be forwarded: _____ (Check if applicable.)

Physician: _____ Responsible Party: _____
Was the physician notified? Date/Time _____ Orders: _____
Responsible Party? Date/Time _____
If the physician and/or responsible party were not notified, please explain why: _____

Describe treatment provided at the facility, physician's office, and/or hospital emergency room: _____

Was the client hospitalized?(circle) Yes No Where? _____
Was the incident reported to other agencies with oversight of the facility/program, e.g., Law Enforcement, Ombudsman, ? No Yes
Agency(ies): _____ By letter(s): _____ phone: _____
fax(s): _____ Date/time: _____ Person(s)Contacted _____
Describe preventive actions, if any, taken by the facility in response to the incident: _____

I certify the above information to be a true and accurate description of the incident.

Signature and title of person making report

Date

R61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 206.2:

A record of each accident and/or incident occurring in the facility, including medication errors and adverse drug reactions, shall be retained. Incidents resulting in death or serious injury, e.g., a broken limb, shall be reported, in writing, to the Division of Health Licensing within ten days of the occurrence.

R61-17, Standards for Licensing Nursing Homes, Section B.(7) and R61-13, Standards for Licensing Habilitation Centers for the Mentally Retarded or Persons with Related Conditions, Section B.(7):

- (a) A record of each accident and/or incident, involving residents, staff or visitors, occurring in the facility or on facility grounds shall be retained. Accidents/Incidents resulting in death or serious injury shall be reported in writing to the Division of Health Licensing within ten days of the occurrence.
- (b) Serious injuries shall be considered as, but not limited to fractures of major limbs or joints, severe burns, severe lacerations, severe hematomas, and suspected abuse.
- (c) All accidents/incidents shall be reviewed, investigated if necessary and evaluated in accord with facility policy.

R61-84, Standards for Licensing Community Residential Care Facilities, Section 903, in part,:

Incidents, accidents and/or sudden illness resulting in death, and serious injury or illness requiring hospitalization shall be reported, in writing to the Division of Health Licensing of the department within 10 days of the occurrence.

R61-91, Standards for Licensing Ambulatory Surgical Facilities, Section 304. H.:

The following essential documents and references shall be on file in the administrative office of the facility: . . .

- H. A record of each accident or incident occurring in the facility, including medications errors, and adverse drug reactions. Incidents resulting in serious injury or death shall be reported, in writing, to the licensing agency within 10 days of the occurrence.

R61-103, Standards For Licensing Residential Treatment Facilities for Children and Adolescents, Section C.(4)(h):

The following essential documents and references shall be on file in the administrative office of the facility:

- (h) a record of each accident or incident occurring in the facility, including medications errors and drug reactions. Incidents resulting in hospitalization or death shall be reported in writing to the Department within 10 days.

R61-93, Standards for Licensing Outpatient facilities for Chemically Dependent or Addicted Persons, Section 302.C:

The administrator shall take all reasonable precautions to assure that no client is exposed to, or instigates such behavior as might be physically or emotionally injurious to himself or to another person at the facility.

1. The facility shall have written plans outlining measures to be taken when any incident resulting in injury or death occurs at the facility.
2. Such incident shall be reported in writing to the S.C. Department of Health and Environmental Control within 5 days of the occurrence.

R61-75, Standards for Licensing Day Care Facilities for Adults, Section F.(3)(d):

(d) Incident and Accident reports: A record of each accident or incident occurring in the facility shall be prepared immediately. Accidents resulting in serious injury or death shall be reported, in writing, to the Department within 10 days of the occurrence.

R61-97, Standards for Licensing Renal Dialysis Facilities, Section 310:

A record of each accident or incident occurring in the facility, including medication errors and adverse drug reactions shall be prepared immediately. Accidents resulting in serious injury or death shall be reported, in writing, to the licensing agency within 10 days of the occurrence. Accidents and incidents that must be recorded include but are not limited to:

- A. Those leading to hospitalization;
- B. Those leading to death;
- C. Use of the wrong dialyzer on patient;
- D. Blood spills of more than 75ml.;
- E. Hemolytic transfusion reactions;
- F. Reactions to dialyzers.



2600 Bull Street
Columbia, SC 29201-1708

October 27, 1998

MEMORANDUM

TO: Administrators, Facilities/Activities Licensed by the Department

FROM: Jerry L. Paul, Director 
Health Licensing Section

SUBJECT: Conditions that will allow a Provider-Wide Partial Exception to the Requirements of Regulations 61-84 and 90, and Clarification of Requirements of Regulations 61-13, 16, 17, 75, 77, 78, 91, 93, 97, 102, and 103

Standards outlined in Regulation 61-84, Standards for Licensing Community Residential Care Facilities, Section 204.B; and Regulation 61-90, Standards for Licensing Chiropractic Facilities, Section 204, require that physical examinations for employees prior to employment be conducted by a physician. This standard has been routinely surveyed during licensing inspections for indications that the physicals have been accomplished and by a physician.

Standards outlined in Regulation 61-13, Standards for Licensing Habilitation Centers for the Mentally Retarded or Persons with Related Conditions, Section B(4)(b); Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 204.B; Regulation 61-17, Standards for Licensing Nursing Homes, Section B(4)(b); Regulation 61-75, Standards for Licensing Day Care Facilities for Adults, Section C.5.g; Regulation 61-77, Standards for Licensing Home Health Agencies, Section 301.E; Regulation 61-78, Standards for Licensing Hospices, Section 301.B; Regulation 61-91, Minimum Standards for Licensing Ambulatory Surgical Facilities, Section 305; Regulation 61-93, Standards for Licensing Outpatient Facilities for Chemically Dependent or Addicted Persons, Section 204.B; Regulation 61-97, Standards for Licensing Renal Dialysis Facilities, Section 305; Regulation 61-102, Standards for Licensing Birthing Centers for Deliveries by Midwives, Section C.5.a; and Regulation 61-103, Standards for Licensing Residential Treatment Facilities for Children and Adolescents, Section C(5)(a), require that physical examinations for employees be conducted prior to employment. These standards, however, do not address who will conduct the physical.

In the interest of establishing reasonable standards which do not compromise the health, safety, and well-being of clients/participants/patients/residents receiving care/treatment in the above facilities/activities, it has been determined that an alternative standard will be allowed.

All facilities/activities referred to above must meet either the standards outlined in their respective licensing standards, **OR**, as an alternative:

In order to insure that a new employee is medically capable of performing his/her job duties, a health assessment, to include required tuberculin skin testing, shall be conducted prior to direct client/participant/patient/resident contact by one of the following:

- 1) Medical Doctor or Doctor of Osteopathy;
- 2) Physician's Assistant;
- 3) Nurse Practitioner;
- 4) Registered Nurse, pursuant to standing orders approved by a physician as evidenced by the physician's signature. The standing orders must be reviewed annually, with a copy maintained at the facility/activity.

This exception does not change any other standards not specifically addressed in this memorandum. The standards in the above-referenced sections of the appropriate regulations will be enforced during licensing inspections, as required either by the applicable regulation or this provider-wide exception. This exception applies to any of the above facilities/activities licensed by this Department, and relates solely to South Carolina licensing standards. Any adverse condition(s) that may be related to this exception may result in its revocation by the Department.

Should you have any questions, please call (803) 737-7370.

JLP:GM:

cc:	Alice Truluck, SCDHEC	SC Health Care Association
	Karen Price, Bureau of Certification	SC Home Care Association
	SC Adult Day Services Association	SC Hospital Association
	SC Assoc for Res Care Homes	Hospice for the Carolinas
	SC Board of Nursing	Renal Dialysis Advisory Council
	SCDAODAS	Residential Care Committee
	SC Freestanding Amb Surg Ctr Assoc	SCDDSN
	SCDMH	SCDSS



December 7, 1998

MEMORANDUM

TO: Administrators of Hospitals, Nursing Homes, Chiropractic Facilities, Community Residential Care Facilities, Intermediate Care Facilities for the Mentally Retarded, Residential Treatment Facilities for Children and Adolescents, Ambulatory Surgical Facilities, Day Care Facilities for Adults, Outpatient Facilities for Chemically Dependent or Addicted Persons, and Renal Dialysis Facilities

FROM: Jerry L. Paul, Director
Health Licensing Section

SUBJECT: Notification of Temporary Facility Closure and Zero Census

If a facility temporarily closes for any reason, e.g., major painting of the facility interior, storm damage, etc., the Department must be given written notice within a reasonable time in advance of closure. This notification must at least include the reason for the temporary closure, where the residents/patients/clients/participants have been/will be transferred, the manner in which the records are being stored, and the anticipated date for re-opening. This office will consider, upon appropriate review of the situation, the necessity to inspect the facility prior to its re-opening, as authorized by the regulation governing the licensing and inspection of the facility.

In addition, in instances when there have been no residents/patients/clients/participants in a facility for a period of 90 days or more for any reason, e.g., unable to secure new admissions, experiencing financial difficulties, etc., the facility must notify the Department in writing that there have been no admission, no later than the 100th calendar day following the date of departure of the last active resident/patient/client/participant. At the time of that notification, this office will consider, upon appropriate review of the situation, the necessity to inspect the facility prior to any new and/or re-admissions to the facility, as authorized by the regulation governing the licensing and inspection of the facility.

The above-referenced notices shall be sent to the Health Licensing Section, DHEC, 2600 Bull St. Columbia, SC 29201. A notice may be faxed to 803-737-7212. If there are questions, please call 803-737-7370.

JLP/JML/gm

cc: Certification Branch
Office of Fire and Life Safety
Office of Certification of Need



2600 Bull Street
Columbia, SC 29201-1708

February 8, 1999

MEMORANDUM

TO: Hospital Administrators

FROM: Jerry L. Paul, Director
Health Licensing Section

SUBJECT: Provider-Wide Exception Dated December 21, 1994, Regarding Authentication of Verbal Orders by Prescribers

Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 601.6, requires: "All medical records shall contain the orders for medication and treatment written in ink and signed by the prescriber or his designee. All orders, including verbal orders, shall be properly recorded in the medical record and dated and signed by the prescriber or designee within 48 hours."

On December 21, 1994, our Section issued a provider-wide exception (PWE) which established an alternative to the requirement that verbal orders be signed by the prescriber within 48 hours. Please review the enclosed copy of the PWE for details related to this exception.

Recent clarification from the Region IV Health Care Financing Administration of the US Department of Health & Human Services indicates that hospitals implementing the December 21, 1994, PWE are out of compliance with The Medicare Conditions of Participation for Hospitals. **Thus, if your hospital participates in the Title XVIII or Title XIX reimbursement programs you do not have the option of adopting the PWE.** If your hospital does not participate in the Title XVIII or Title XIX reimbursement programs you may adopt, or continue implementation of, the PWE.

During licensing inspections Section staff will review facility policies and procedures to determine whether your hospital has adopted the PWE or not, and will enforce during inspections, your adherence to the standards of R61-16, Section 601.6 or the PWE, as per your policies and procedures.

If there are any questions, please call Dennis Gibbs at (803) 737-7370.

JLP:DG:dg

Enclosure

cc: Doug Bryant, Commissioner
Alice Truluck, DHEC
Trudy Solomon, SCHA

Karen Price, DHEC
Karen Reeves, SCHA



2600 Bull Street
Columbia, SC 29201-1708

April 19, 1999

MEMORANDUM

TO: Administrators of Ambulatory Surgical Facilities, Chiropractic Facilities, Community Residential Care Facilities, Hospitals and Institutional General Infirmaries, and Residential Treatment Facilities for Children and Adolescents

FROM: Jerry L. Paul, Director
Health Licensing Section

SUBJECT: Conditions Allowing a Provider-wide Exception to the Requirements of Regulation 61-91, Ambulatory Surgical Facilities, Section 2501.B; Regulation 61-90, Chiropractic Facilities, Section 1801.B; Regulation 61-84, Standards for Licensing Community Residential Care Facilities, Section 2401.B; Regulation 61-16, Hospitals and Institutional General Infirmaries, Section 2501.B; Regulation 61-103, Residential Treatment Facilities for Children and Adolescents, Section P(1)(b)

NOTE: This exception replaces a similar exception for community residential care facilities issued by the Department on July 17, 1998.

Regulation 61-91, Section 2501.B, requires that, "Exits shall be placed so that the entrance door of every room and every point in surgical suites, recovery rooms, lounges, dining rooms, etc., shall be not more than 100 feet along the line of travel from the nearest exit. In buildings equipped with automatic sprinklers this distance shall be not more than 150 feet." Regulation 61-90, Section 1801.B and Regulation 61-16, Section 2501.B require that "Exits shall be place so that the entrance door of every private room and sem-private room, and every point in open wards, day rooms, dormitories, dining rooms, et cetera, shall not be more than 100 feet along the line of travel from the nearest exit. In building equipped with automatic sprinklers this distance shall not be more than 150 feet." Regulation 61-84, Section 2401.B requires that "Exits shall be place so that the entrance door of every private room and semiprivate room and every pont shall be not more than 100 feet along the line of travel to the nearest exit." Regulation 61-103, Section P (1)(b) requires that "Exits shall be placed so that the entrance door of every private room and semi-private room shall be not more than 100 feet along the line of travel to the nearest exit."

Page 2
PWE - Exits
April 14, 1999

Having reviewed the most recent Standard Building Code requirements for travel distances for the occupancy categories in the above facilities, it has been determined that the distances indicated in each respective regulation may be excessively restrictive. In the interest of establishing reasonable standards which can be met by providers and yet do not compromise the health and well-being of patients cared for in the above facilities, it has been determined that alternative standards will be considered as acceptable.

All ambulatory surgical facilities, chiropractic facilities, community residential care facilities, hospitals and institutional general infirmaries, and residential treatment facilities for children and adolescents will be required to meet the standard outlined in each facility's respective licensing standard, i.e., R61-91, Section 2501.B, R61-90, Section 1801.B, R61-84, Section 2401.B, R61-16, Section 2501.B; or R61-103, Section P (1)(b), or, as an alternative:

Exits shall be so located that the travel distance to the most remote point in a floor area, room or space to the nearest exit, along the line of travel, shall be no more than the travel distance specified by occupancy type as defined in the Standard Building Code.

NOTE: In facilities that are surveyed for federal reimbursement by the Health Care Finance Administration (HCFA), the maximum travel distance shall be the shortest of the requirements of the Standard Building Code and the Life Safety Code (National Fire Protection Association 101).

These exceptions apply to any ambulatory surgical facility, chiropractic facility, community residential care facility, hospital or institutional general infirmary, or residential treatment facility for children and adolescents licensed by the Department. It relates solely to SC licensing standards. Any adverse condition(s) that may be related to this exception may result in revocation of the exception by the Department.

If there are any questions, you may call Mr. William Lafferty at (803) 737-7663.

JPL/JML

cc: Alice Truluck
Bill Trawick, SCANPHA
Sandra Lynn, SCARCH
Ken Schull, SCHA
Ann Geier, FASC
William Lafferty



2600 Bull Street
Columbia, SC 29201-1708

August 11, 1999

MEMORANDUM

TO: Hospital Administrators

FROM: Jerry L. Paul, Director
Health Licensing Section

SUBJECT: New South Carolina Code Effecting Licensing Standards

Regulation 61-16, Standards for Licensing Hospitals and Institutional General Infirmaries, Section 601.6, establishes certain standards on the subject of prescriber signatures on verbal orders. On December 21, 1994, the Department issued a provider-wide partial exception to the requirements outlined in Section 601.6 of R61-16.

Effective June 11, 1999, Section 44-30-90 of the S. C. Code Ann. 1976, as amended, was modified to read as follows: (Indicates New Matter) "The department and each licensing board shall promulgate regulations necessary to accomplish the purposes set forth in this chapter and to comply with the public law no later than October 1, 1992. All orders for medication dispensed or treatment provided in a hospital shall be authenticated according to hospital policy. The orders shall be taken by personnel qualified by hospital medical staff rules and shall include the date, time and name of persons who gave the order, and the signature of the person taking the order. The Department of Health and Environmental Control shall promulgate regulations consistent with this provision." S. C. Code Ann. 1976, as amended, Section 44-30-90 supercedes the standards established in Section 601.6 of R61-16 and in the December 21, 1994, provider-wide partial exception.

Effective immediately, for the purposes of compliance with state licensing standards and in accordance with state law, hospitals which have established written policies regarding when verbal orders must be authenticated by prescribers will be required to comply with their policies on this subject. (Hospitals which implemented the December 21, 1999, provider-wide exception already meet the requirement for policies regarding when verbal orders must be authenticated but may wish to modify their policies at this time.) Hospitals which have not established policies regarding when verbal orders must be authenticated by prescribers shall comply with Section 601.6 of R61-16.

Should you have any licensing questions, please call Dennis Gibbs at (803) 737-7370. Should you have questions regarding compliance with The Medicare Conditions of Participation for Hospitals, please call Certification Branch staff at (803) 737-7205.

JLP:DLG:dg

cc: Doug Bryant, DHEC
Karen Price, DHEC
Jim Walker, SCHA

Flo Tumbokon, DHEC
Wilbur Harling, DHEC

Alice Truluck, DHEC
Nancy Layman, DHEC



2600 Bull Street
Columbia, SC 29201-1708

December 8, 2003

MEMORANDUM

TO: Hospital; Nursing Home; Intermediate Care Facility for the Mentally Retarded; and, Community Residential Care Facility Administrators

FROM: Leon Frishman, Deputy Commissioner *Leon B. Frishman*
Health Regulations

SUBJECT: Licensed Bed Capacity During An Emergency

Standards regarding maximum bed capacity are established in the licensing regulations for hospitals, nursing homes, intermediate care facilities for the mentally retarded and community residential care facilities. An example of one such standard is found at § 501. of Regulation 61-16, Standards for Licensing Hospitals & Institutional General Infirmaries, "No facility shall have set up or in use at any time more beds than the number stated on the face of the license except in cases of justified emergencies..." Furthermore, § 502. of Regulation 61-16, addresses the location of beds, "Beds shall not be placed in corridors, solaria or other locations not designated as patient room areas except in cases of justifiable emergencies." Due to recent inquiries the Department is providing guidance on emergency situations and when additional beds (over and above licensed bed capacity) may be set up and utilized.

A facility desiring to temporarily admit patients/residents in excess of licensed bed capacity due to an emergency should do the following:

1. Request that the Department concur that an emergency situation does exist by contacting the:
 - a. Director of the Division of Health Licensing at (803) 545-4370, or;
 - b. Director of the Bureau of Health Facilities Regulation at (803) 545-4370, or;
 - c. Assistant Deputy Commissioner for Health Regulations at (803) 545-4200.
2. The facility should be prepared to:
 - a. outline the maximum number of patients/residents to be temporarily admitted, and;
 - b. an anticipated date for discharge of the temporary patients/residents, and;
 - c. how and where the temporary patients/residents will be housed.

MEMORANDUM

December 8, 2003

Page 2

3. Patients/residents temporarily admitted during a declared disaster will not be required to undergo tuberculin screening or submit to an admission history and physical examination.
4. The facility shall notify the Department when the temporary patients/residents have been discharged.

Other issues such as who will staff the care of the temporary patients/residents, physician orders, additional food for the temporary patients/residents, and handling of medications should be resolved ahead of time by memorandums of agreement, internal policies and procedures, etc.

If we may be of further assistance on this subject, please contact the Division of Health Licensing at (803) 545-4370.

cc: James R. Walker, Jr., SCHA
J. Randall Lee, SCHCA
Vicki Moody, SCANPHA
Karen Price, DHEC
Beverly Patterson, DHEC
Nancy Layman, DHEC
DHEC DA's

Melody Rawls, SCARCH
P. Scott Jones, SCNHA
Brad Beasley, SCDDSN
Kevin Ridenour, DHEC
Shirley Hollingsworth, DHEC
John Simkovich, DHEC
DHEC DMD's

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Promoting and protecting the health of the public and the environment.

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Coleman F. Buckhouse, MD

September 22, 2005

MEMORANDUM

TO: Administrators of Hospitals, Nursing Homes, Intermediate Care Facilities,
Hospice Inpatient Facilities

FROM: Dennis L. Gibbs, Director
Division of Health Licensing

SUBJECT: Conditions Allowing a Provider-wide Exception to the Requirements of Regulation 61-16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries, Section 504.; Regulation 61-17, Standards for Licensing Nursing Homes, Section D.(6)(b); Regulation 61-13, Habilitation Centers For The Mentally Retarded or Persons With Related Conditions, Section D.(6)(b); Regulation 61-78, Standards for Licensing Hospices, Section 2406.B.

Regulation 61-16, Section 504. requires that, "Hospitals shall provide oxygen for the treatment of patients. When oxygen is dispensed, administered or stored, adequate safety precautions against fire and other hazards shall be exercised. "No Smoking" signs shall be posted conspicuously and cylinders shall be properly secured in place." Regulation 61-17, Section D.(6)(b) requires that, "When oxygen is dispensed, administered or stored, adequate safety precautions against fire and other hazards shall be exercised. "No Smoking" signs shall be posted conspicuously. All cylinders shall be secured." Regulation 61-13, Section D.(6)(b) requires that, "When oxygen is dispensed, administered or stored, adequate safety precautions against fire and other hazards shall be exercised. "No Smoking" signs shall be posted conspicuously. Cylinders shall be secured." Regulation 61-78, Section 2406.B. requires that, "Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place."

Smoking in healthcare facilities may result in fires and the adoption and enforcement of appropriate smoking policies is essential for effective fire prevention. Many licensed facilities have established "No Smoking" policies and procedures that is an important step in improving the level of fire safety in healthcare facilities. The National Fire Protection Association (NFPA) 99, Standard for Healthcare Facilities, 2002 edition, Section 9.6.3.2.2 states, "In health care facilities where smoking is prohibited and signs are (strategically) placed at all major entrances, secondary signs with no-smoking language shall not be required." Additionally, Section 9.6.3.2.3 states, "The nonsmoking policies shall be strictly enforced."

In the interest of establishing reasonable standards which can be met by providers and yet do not compromise the health and well-being of patients, residents, or clients cared for in the above facilities, it has been determined that alternative standards will be considered as acceptable. All hospitals, nursing homes, intermediate care facilities, and hospice inpatient facilities will be required to meet the standard outlined in each facility's respective licensing standard, *i.e.*, Regulation 61-16, Section 504; Regulation 61-17, Section D.(6)(b); Regulation 61-13, Section D.(6)(b); Regulation 61-78, Section 2406.B., or, as an alternative:

Only in "Smoke-Free" facilities, "No Smoking" signs shall not be required in and in the vicinity of patient, resident, or client bedrooms where oxygen is being administered provided all 3 of the following conditions are met:

1. Smoking is prohibited; and
2. The facility nonsmoking policy is strictly enforced; and
3. "Smoke-Free" signs are strategically placed at all major entrances.

"No Smoking" signs will still be required in and in the vicinity of patient, resident, or client bedrooms where oxygen is being **stored, as well as all other required areas of the facility.**

These exceptions apply to any hospital, nursing home, intermediate care facilities, or hospice inpatient facility licensed by the Department. It relates solely to SC licensing standards. Any adverse condition(s) that may be related to these exceptions may result in revocation of these exceptions by the Department.

If there are questions, please call 803-545-4370.

DLG/REL/jml

cc: Bureau of Certification
Fire and Life Safety Program
Division of Certification of Need

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
REGULATION 61-16
MINIMUM STANDARDS FOR LICENSING HOSPITALS
AND INSTITUTIONAL GENERAL INFIRMARIES

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**SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
REGULATION 61-16
MINIMUM STANDARDS FOR LICENSING HOSPITALS
AND INSTITUTIONAL GENERAL INFIRMARIES**

PART I - ADMINISTRATION

CHAPTER 1 - DEFINITIONS AND INTERPRETATIONS

SECTION 101. DEFINITIONS:

For the purpose of these Standards, the following definitions shall apply:

A. The Department: The South Carolina Department of Health and Environmental Control.

B. Licensee: The "Licensee" is the individual with whom rests the ultimate responsibility for maintaining approved standards for the facility.

C. Patient: The term "patient" shall mean any individual who is being treated by a physician in a hospital.

D. Definition of Facilities: For administrative purposes, hospitals and institutional general infirmaries in S.C. which are subject to licensure laws as required by Section 44-7-310 **[See Note]** of the Code of Laws of S.C. of 1976, shall be defined and classified as follows:

[Note: This reference, as printed in the State Register, is incorrect. The correct reference is 44-7-260]

1. General Hospital: A "general hospital" is a facility with an organized medical staff to maintain and operate organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and care of such persons over a period exceeding 24 hours and provides medical and surgical care of acute illness, injury or infirmity and may provide obstetrical care, and in which all diagnoses, treatment or care are administered by or performed under the direction of persons currently licensed to practice medicine and surgery in the State of S.C.

2. Specialized Hospital: A "specialized hospital" is a facility which has an organized medical staff, maintains and operates organized facilities and services to accommodate two or more nonrelated persons for the diagnosis, treatment and/or care of such persons over a period exceeding 24 hours and which provides a specialized service for one type of care, such as tuberculosis, maternity, orthopedics, pediatrics, E.E.N.T., etc., and in which all diagnoses, treatment or care are under the direction of persons currently licensed to practice medicine and surgery in the State of S.C.

3. Institutional General Infirmary: An “institutional general infirmary” is a facility which is established within the jurisdiction of a larger nonmedical institution and which maintains and operates organized facilities and services to accommodate two or more nonrelated students, residents or inmates with illness, injury or infirmity for a period exceeding 24 hours for the diagnosis, treatment and care of such persons and which provides medical, surgical and professional nursing care, and in which all diagnoses, treatment and care are performed under the direction of persons currently licensed to practice medicine and surgery in the State of S.C.

4. Chronic Hospital: A “chronic hospital” is a facility which has an organized medical staff and provides skilled nursing and other services in facilities designed and equipped for diagnosis and treatment over a period exceeding 24 hours of two or more nonrelated persons who have chronic diseases. This includes, as a minimum, diagnostic x-ray services, minor surgery, clinical laboratory and rehabilitation services if the licensee does not already operate these services in a physically attached facility.

5. Public Health Centers: A “public health center” means a publicly owned facility for the provision of public health services, including related facilities such as laboratories, clinics and administrative offices operated in connection with such facilities.

6. Diagnostic and Treatment Centers: The term “diagnostic or treatment center” means a facility for the diagnosis and treatment of ambulatory patients (a) which is operated in connection with a hospital, or (b) in which patient care is under the professional supervision of persons licensed to practice medicine or surgery within the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry within the State.

7. Rehabilitation Facilities: The term “rehabilitation facility” means a facility which is operated for the rehabilitation of disabled persons through an integrated program of: (a) medical evaluation services, and (b) psychological, social or vocational evaluation services, under competent professional supervision, and in the case of which, (c) the major portion of the required evaluation and services is furnished within the facility, and (d) either (1) the facility is operated in connection with a hospital, or (2) all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State of S.C.

8. Privately-Owned Educational Institutional Infirmary: The term “privately-owned educational institutional infirmary” within the scope of the Licensing Standards is defined as a privately owned college infirmary.

E. Designee: A physician, dentist, osteopath or podiatrist, who has staff privileges, selected by a prescriber to sign verbal orders for medication or treatment in the prescriber’s absence.

F. Existing Facility An “existing facility” is one which was in operation and/or one which began the construction or renovation of a building, for the purpose of operating the facility,

prior to the adoption of these Standards. The Licensing Standards governing new facilities apply if and when an existing facility is not continuously operated and licensed under these Standards.

G. New Facilities: A “new facility” is one which began operation and/or one which began construction or renovation of a building for the purpose of operating the facility after the adoption of these Standards.

H. Attic: The term “attic” when used in these Standards shall mean the space between the finished ceiling of the top habitable story and the roof sheathing or decking.

I. Basement: The term “basement” shall mean that portion of the building having less than half its clear height above the average grade of the adjoining ground.

J. Story: The term “story” shall mean that portion of a building included between the upper surface of any floor and the under surface of the floor or roof next above. For the purpose of these Standards, this definition does not apply to basements.

K. Multistory: For the purposes of these Standards, the term “multistory” shall mean more than one story.

L. First Floor: The term “first floor” shall be that story which is of such height above grade that it does not come within the definition of a basement or shall be that story located immediately above a basement.

M. Exit: “Exit” is that portion of a means of egress which is separated from the area of the building from which escape is to be made by walls, floors, doors or other means which provide the protected path necessary for the occupants to proceed with safety to the exterior of the building.

N. Fire-resistive Rating: The term “fire-resistive rating” shall mean time in hours or fractions thereof that materials or their assemblies will resist fire exposure as determined by fire tests conducted in compliance with recognized standards, i.e., ASTM and NFPA.

O. Automatic Sprinkler System: The term “automatic sprinkler system” shall mean an arrangement of piping and sprinklers designed to operate automatically by the heat of fire and to discharge water upon the fire.

SECTION 102. INTERPRETATIONS:

A. License: A license is issued pursuant to the provisions of the S.C. Code Ann. § 44-7-250 through 44-7-340 (Supp. 1989) and the Licensing Standards promulgated thereunder and shall be posted in a conspicuous place in a public lobby or waiting room.

B. Effective Date and Term of License:

1. A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility which has not been inspected by the Department during that year may continue to operate under its existing license until an inspection is made.

2. For purposes of these regulations the Department may rely on the survey of the Joint Commission on Accreditation of Hospitals (JCAH), and related documents, to satisfy in part the hospital relicensure inspection requirements.

a. A hospital desiring to participate in this procedure shall provide the Department with:

(1) Written notice of its desire, no later than 3 months prior to expiration of its license (this notice must include a statement that the hospital “hereby authorizes the Joint Commission on Accreditation of Hospitals to provide to the Department any information which the Department may request from the JCAH.”);

(2) A copy of its last JCAH survey report and accreditation decision, complete with enclosures;

(3) If applicable, copies of any appeals, progress reports, reports of JCAH focused surveys (and complaint investigations), and related correspondence;

(4) A copy of the Application for Survey and Hospital Survey Profile related to the next JCAH survey;

(5) A copy of the JCAH notification of next survey.

b. The notice of a hospital's desire to participate, as described in a.(1) above, is required only for the calendar year in which a JCAH survey is expected.

c. All other documentation, as described in a.(2)-(5) above, shall be furnished to the Department immediately upon its availability to the hospital, on a continuing basis.

3. Notwithstanding the provisions contained in Section 102.B.2, the Department shall, at its discretion, conduct such inspections and investigations and require compliance with these Standards in accordance with the provisions of these regulations.

C. Separate Licenses: Separate licenses are required for hospitals which also provide separate buildings, wings or floors, and/or services, to accommodate nursing and intermediate care patients.

D. Facilities Exempt from the Standards:

1. Privately owned educational facilities maintaining infirmaries for the exclusive use of their student bodies as herein defined;

2. Hospitals maintained by the Federal Government.

E. Inspections: All facilities to which these requirements apply shall be subject to inspection at any time without prior notice by properly identified personnel of the Department.

F. Initial License: A new facility, or one that has not been continuously licensed under these or prior Standards, shall not admit patients until it has been issued an initial license. This initial license shall be termed a "Provisional License" and shall expire 90 days from date of issue or until re-surveyed for licensure. To determine that the facility is functioning in compliance with these Standards, the Department shall reinspect the facility prior to expiration of the provisional license. Substantial compliance with these Standards under actual operating conditions shall be verified by the Department prior to issue of a license which shall expire one year from the date of issue of the provisional license. (See Appendix A, Prerequisites for Initial Licensure.)

G. Noncompliance: When noncompliances of the Licensing Standards are detected by means of inspections or investigations, the licensee will be notified of the violations and at the same time requested to provide information as to when and how such items will be corrected. If an item of noncompliance is of a serious nature and is not promptly corrected, a penalty may be invoked or a license may be denied, suspended, or revoked.

H. Application: Applicants for a license shall file application under oath annually with the Department. An application shall be signed by the owner, if an individual or partnership; or in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in case his address is different from that of the facility; the names of persons in control thereof and such additional information as the Department may require, including affirmative evidence of ability to comply with reasonable standards, rules and regulations as may be lawfully prescribed. No proposed hospital shall be named nor may an existing hospital have its name changed to the same or similar name as a hospital licensed in the State.

I. Licensing Fees: Each applicant shall pay an annual license fee prior to issuance of a license. For licenses issued through December 31, 1991, the annual fee shall be \$50.00 for the first ten beds and \$0.25 for each additional bed. For licenses issued in calendar year 1992, the annual fee shall be \$3.00 for each licensed bed. For licenses issued in calendar year 1993, the annual fee shall be \$5.00 for each licensed bed. For licenses issued on and after January 1, 1994, the annual fee shall be \$10.00 for each licensed bed.

J. Exceptions to Licensing Standards: The Department reserves the right to make exceptions to these Standards where it is determined that the health and welfare of the community requires the services of the facility. When an "Exception" applies to an existing facility, it will continue to meet the Standards in effect at the time it was licensed.

K. Change of License: A facility shall request issue of an amended license, by letter to the Department prior to any of the following circumstances:

1. Change of ownership by purchase or lease;
2. Change of facility's name;
3. Addition or replacement of beds (compliance with Appendix A and an inspection are required prior to issuance of license);
4. Deletion of beds;
5. Reallocation of types of beds as shown on license.

SECTION 103. CLASSIFICATION OF LICENSES:

The following types of licenses will be issued:

A. Class I: Facilities that have a majority of their beds housed in a structure which meets the appropriate rating for fire safety.

B. Class II: Facilities that have a majority of their beds housed in a structure which does not meet the appropriate rating for fire safety but is equipped with an approved automatic sprinkler system.

SECTION 104. CERTIFICATION TO PERFORM ABORTIONS:

Upon receipt of a written request from the hospital authorities to the Department requesting such certification, any general hospital having a current license to operate may be certified as a suitable facility for the performance of abortions. (§44-41-10(d) of the S.C. Code of Laws of 1976.)

SECTION 105. PENALTIES:

The department may deny, suspend, or revoke licenses or assess a monetary penalty for violations of provisions of law or departmental regulations. The department shall exercise discretion in arriving at its decision to take any of these actions. The department will consider the following factors: specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions. The classification of violations (i.e., Class I, II, or III) is included in Appendix B to this regulation. If a decision is made to assess monetary penalties, the following schedule will be used as a guide to determine the dollar amount:

Frequency of

violation of

standard within a

MONETARY PENALTY RANGES

24-month period	Class I	Class II	Class III
1st	\$ 200-1000	\$ 100- 500	\$ 0
2nd	500-2000	200-1000	100- 500
3rd	1000-5000	500-2000	200-1000
4th	5000	1000-5000	500-2000
5th	5000	5000	1000-5000
6th and more	5000	5000	5000

A. Class I violations are those which the Department determines present an imminent danger to the patients of the facility or a substantial probability that death or serious harm could result therefrom. A physical condition, one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

B. Class II violations are those which the Department determines have a direct or immediate relationship to the health, safety or security of the facility's patients other than Class I violations. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

C. Class III violations are those which are not classified as serious in these regulations or those which are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

D. Violations of §44-7-320(A)(2) and (4) **[See Note]** of the S.C. Code of Laws of 1976, as amended, quoted below, are considered Class I violations:

[Note: This reference, as printed in the State Register, is incorrect. The correct reference is 44-7-320(A)(1)(b) and (A)(1)(d)]

“(2) Permitting, aiding, or abetting the commission of any unlawful act relating to the securing of a Certificate of Need or the establishment, maintenance, or operation of a facility requiring certification of need or licensure under this article;”

“(4) Refusing to admit and treat alcoholic and substance abusers, the mentally ill, or mentally retarded, whose admission or treatment has been prescribed by a physician who is a member of the facility's medical staff; or discriminating against alcoholics, the mentally ill, or mentally retarded solely because of the alcoholism, mental illness, or mental retardation.”

CHAPTER 2 - MANAGEMENT

SECTION 201. GENERAL:

Every facility shall be organized, equipped, manned and administered in order that adequate care may be provided for each person admitted. No proposed hospital shall be named nor may any existing hospital have its name changed to the same or similar name as a hospital licensed in the State.

SECTION 202. CONTROL:

The governing board, or the owner, or the person or persons designated by the owner as the governing authority shall be the supreme authority in the hospital responsible for the management control of the hospital and appointment of the medical staff. A written set of bylaws for operation of the hospital shall be formulated by the governing authority. Committees as determined by the needs and services of the hospital shall be provided, e.g., safety, infection control, pharmacy and therapeutic, tissue. The medical staff shall be responsible to the governing authority for the clinical and scientific work of the hospital.

SECTION 203. CHIEF ADMINISTRATIVE OFFICER:

The chief administrative officer shall be selected by the governing body or owner and shall have charge of and be responsible for the administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the chief administrative officer shall be reported immediately by the governing body or owner to the Department in writing.

SECTION 204. EMPLOYEES:

A. Qualified personnel shall be employed in sufficient numbers to carry out the functions of the hospital. The licensee shall obtain written applications for employment from all employees. Such applications for employment shall contain accurate information as to age, education, training, experience, health and personal background of each employee. All applications for licensed personnel shall contain the S.C. license number and/or current renewal number, if applicable.

B. All new employees and volunteers who have contact with patients shall have a physical examination within one year prior to employment. No more than three months prior to employment, all new employees and volunteers who have contact with patients shall undergo a tuberculin skin test, unless a previously positive reaction can be documented. The intradermal (Mantoux) method, using five tuberculin units (TU) of stabilized purified protein derivative (PPD) is to be used. Employees and volunteers with tuberculin test reactions of 10mm or more of induration should be referred for appropriate evaluation. The two-step procedure is advisable for initial testing in those who are 55 years of age and older in order to establish a reliable baseline.

1. Employees and volunteers with reactions of 10mm and over to the pre-employment tuberculin test, those who are documented with previously positive reactions, those with newly converted skin tests and those with symptoms suggestive of tuberculosis (e.g., cough, weight loss, night sweats, or fever, etc.) regardless of skin test status, shall be given a chest radiograph to determine whether tuberculosis disease is present. If tuberculosis is diagnosed, appropriate treatment should be given and contacts examined.

2. There is no need to do initial or routine chest radiographs on employees or volunteers with negative tuberculin tests who are asymptomatic.

3. Employees with negative tuberculin skin tests shall have an annual tuberculin skin test and, depending upon the test results, shall be followed as described in this regulation.

4. New employees or volunteers who have a history of tuberculosis disease shall be required to have certification by a licensed physician that they are not contagious.

5. Regular employees and volunteers who are known or suspected to have tuberculosis shall be required to be evaluated by a licensed physician and will not be allowed to return to work until they have been declared noncontagious.

6. Preventive treatment of now positive reactors without disease should be an essential component of the infection control program. It should be considered for all infected employees and volunteers who have patient contact, unless specifically contraindicated. Routine annual chest radiographs of positive reactors do little to prevent tuberculosis and therefore are not a substitute for preventive treatment.

a. Employees who complete treatment, either for disease or infection, may be exempt from further routine chest radiographic screening unless they have symptoms of tuberculosis.

b. Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest radiograph. These individuals must be informed of their lifelong risk of developing and transmitting tuberculosis to individuals in the institution and in the community. They shall be informed of symptoms which suggest the onset of tuberculosis, and the procedure to follow should such symptoms develop.

7. Post exposure skin tests should be provided for tuberculin negative employees within 12 weeks after termination of contact for any suspected exposure to a documented case of tuberculosis.

8. A person will be designated at each institution to coordinate tuberculosis control activities.

C. Job Orientation: All new personnel shall be oriented to educate them with the organization and environment of the facility, the employees' specific duties and

responsibilities, and patients' needs. Each employee shall be familiar with the facility's emergency disaster plans. (Also, see Sections 207 and 1207.)

D. Inservice Training: Inservice training programs shall be planned and provided for all personnel to insure and maintain their understanding of their duties and responsibilities. Records shall be maintained to reflect program content and individuals attending.

E. Personnel Record: A personnel record folder shall be maintained on file for each employee.

SECTION 205. VOLUNTARY WORKERS:

A. All voluntary workers who handle food or provide patient care shall have a physical examination prior to their initial food handling or patient care activity.

B. For patient care volunteers, the tuberculin testing and treatment program described in Section 204.B also applies.

SECTION 206. REPORTS:

206.1 Fire Report: A complete written report shall be prepared and promptly submitted to the Department for every fire regardless of size or damage that occurs in the facility.

206.2 Accident and/or Incident Report: A record of each accident and/or incident occurring in the facility, including medication errors and adverse drug reactions, shall be retained. Incidents resulting in death or serious injury, e.g., a broken limb, shall be reported, in writing, to the Division of Health Licensing within 10 days of the occurrence.

206.3 Joint Annual Report: The Department requires each health care facility to annually complete a questionnaire named "Joint Annual Report" and return this report within the time period as specified in the report's accompanying cover letter.

SECTION 207. DISASTER PREPAREDNESS:

Each facility shall develop, in coordination with the appropriate fire department, law enforcement agency and/or disaster preparedness agency, an approved written plan to provide for the evacuation and care of mass casualties which may result from natural or man-made disasters. The plan shall be rehearsed at least annually. A record of the rehearsal, including its date and time, a summary of actions and recommendations shall be maintained.

SECTION 208. EMERGENCY CALL DATA:

Emergency call information shall be conspicuously posted to be immediately available to personnel when needed. Emergency call data shall include at least the following information:

- A. Telephone number of fire and police departments;
- B. Name, address, and telephone number of all personnel to be called in case of fire or emergency;
- C. Name, address, and telephone number of physician on call;
- D. Name, address, and telephone number of supervisory personnel, and whereabouts when on call;
- E. Address and telephone number of a poison control center.

SECTION 209. CLIENT-PATIENT PROTECTION ACT:

The notice required by Section 7 of the Client-Patient Protection Act of May 9, 1979, shall be prominently displayed.

SECTION 210. CONTINUITY OF ESSENTIAL SERVICES:

The management of each facility shall develop plans to provide for the continuation of essential patient supportive services in the event of the absence from work of any portion of the work force resulting from inclement weather or other causes.

CHAPTER 3 - MEDICAL STAFF

SECTION 301. APPOINTMENTS:

Each hospital must have a single organized medical staff that has the overall responsibility for the quality of medical care provided to patients. The medical staff shall be appointed by the governing authority in accordance with the hospital's bylaws. Prior to a physician's initial appointment and periodic reappointment, the governing authority shall assure itself that the physician is qualified and competent to practice in his profession. This organized group shall, with the approval of the hospital governing body, adopt bylaws, rules and regulations to govern its operation as an organized medical staff. Hospital bylaws shall contain renewal procedures, authority to limit or terminate staff privileges, and appeal procedures.

SECTION 302. ELIGIBILITY:

To be eligible for membership on a staff an applicant must be licensed to practice in his profession in the State of S.C., competent in his respective field, worthy in character and in matters of professional ethics, and meet the requirements of the hospital's bylaws. Medical staff membership must be limited to doctors of medicine or osteopathy by the State Board of Medical Examiners, dentists licensed to practice dentistry by the State Board of Dentistry and podiatrists licensed to practice podiatry by the State Board of Podiatry Examiners. No individual is automatically entitled to membership on the medical staff or to the exercise of any clinical privilege merely because he is licensed to practice in any state, because he is a member of any professional organization, because he is certified by any clinical examining board, or because he has clinical privileges or staff membership at another hospital without meeting the criteria for membership established by the governing body of the respective hospital.

SECTION 303. MEETINGS:

The medical staff, either as a whole or on a department or clinical service basis, shall meet at a frequency as determined by the facility but no less than every three months to review and analyze their clinical experience. Written minutes of such meetings shall be recorded and filed. There shall be mechanisms in place for monitoring and evaluation the quality of patient care services, for improving services, and for evaluation the effectiveness of improvement efforts.

SECTION 304. TYPES OF STAFFS:

If accepted, an applicant shall be appointed periodically by the governing board and assigned as active staff, associate staff, consulting staff, courtesy staff, honorary staff, resident staff or similar staff classifications.

SECTION 305. DEPARTMENTALIZATION:

In hospitals maintaining organized departments or services, such as medicine, surgery, obstetrics, pediatrics, orthopedics, etc., the medical staff shall elect periodically a chief of staff and staff members to be the responsible heads or chiefs for each department or service, subject to the approval of the governing body. Minutes of all department or service meetings shall be recorded and filed.

SECTION 306. INTERNS AND RESIDENTS:

In compliance with such rules for professional services of interns and resident physicians as the medical staff prescribes, the medical staff shall supervise and direct interns and resident physicians in the diagnosis and treatment of all patients and in the performance of any other professional duties and shall certify them to the governing body and administrative officer.

SECTION 307. SUPERVISION OF PATIENT CARE:

All persons admitted to any facility covered by these Standards must be under the care of a person duly licensed to practice medicine, dentistry or osteopathy. Patients of podiatrists and dentists who are members of the medical staff of a hospital must be co-admitted by a doctor of medicine or osteopathy who is a member of the medical staff of the hospital who shall be responsible for the general medical care of the patient. Oral surgeons who have successfully completed a postgraduate program in oral surgery accredited by a nationally recognized accredited body approved by the U.S. Office of Education may admit patients without the requirement of co-admission if permitted by the bylaws of the hospital and medical staff.

SECTION 308. AVAILABILITY FOR EMERGENCIES:

All hospitals shall have a licensed physician available on call at all times.

SECTION 309. DENIAL OF EMERGENCY CARE:

No person, regardless of his ability to pay, shall be denied emergency care if a member of the hospital medical staff determines that the person is in need of such care.

CHAPTER 4 - NURSING SERVICE

SECTION 401. GENERAL:

The department of nursing shall be organized and staffed at all times to provide total nursing care to each patient. The authority, responsibility and function of each category of nurse shall be clearly defined by written hospital regulations.

SECTION 402. PROFESSIONAL PERSONNEL:

402.1 The hospital shall employ and designate a registered professional nurse currently licensed in S.C. to be in charge of the nursing service. He/She shall be responsible to the administrator for nursing service rendered in the hospital. A registered professional nurse shall be designated to act in his/her absence.

402.2 Additional Professional Registered Nurses: There shall also be a sufficient number of duly licensed registered nurses on duty at all times to plan, assign, supervise, and evaluate nursing care, as well as to give patients the nursing care that requires the judgment and specialized skills of a registered nurse. Depending on the size of the facility and the services rendered, additional professional registered nurses shall be employed as needed to provide supervision and coverage. They shall assume responsibility for the nursing service rendered in such services as the following: Medical, Surgical, Pediatrics, Obstetrical, Nursery, Operating Rooms, Delivery Rooms, Recovery Rooms, Emergency Services, Coronary Care Units and Intensive Care Units.

402.3 Other Nursing Personnel: There shall be other nursing personnel in the facility at all times to provide total care for patients. Licensed practical nurses and all other workers who are employed by a facility in the nursing department shall be assigned only those clearly defined duties for which they are trained.

402.4 Special Duty Nurses: All persons who render special duty nursing service in the hospital shall be under the supervision of the nursing supervisor of the department or service concerned and shall be subject to all rules and regulations of the facility.

402.5 Licensure and Registration of Nurses: All nurses employed in a professional capacity in a facility shall be currently licensed to practice in S.C.

SECTION 403. STAFF MEETINGS:

There shall be regular meetings of the nursing staff at least quarterly to review and analyze the nursing service to determine the quality of the nursing care rendered to patients and to increase the efficiency of the nursing service. Minutes of all meetings should be maintained and readily available.

SECTION 404. NURSING PROCEDURES:

404.1 Procedure Manual: A procedure manual shall be written, reviewed at least annually and revised as necessary in accordance with current accepted practices. A copy shall be available at each nursing station.

404.2 Use of Safety Precautions: There must be a written order to include length of time to be used, signed by the physician approving use of safety precautions either at the time they are applied to a patient, or in case of emergency, within 24 hours after they have been applied. The licensee shall post instructions in each procedure manual on the specific types of safety precautions that may or may not be used.

404.3 Administration of Medications:

A. Drugs shall be administered only upon the order of a physician, dentist, osteopath or podiatrist who has been granted medical staff privileges. Such orders shall be properly recorded in the medical record and signed by the prescriber or his designee.

B. Verbal and telephone orders shall be given only to a licensed nurse and immediately recorded, dated and signed. This restriction shall not be construed to prohibit the issuance and acceptance of verbal orders in other specialized departments or services as authorized in the medical staff by-laws, e.g., orders pertaining to respiratory therapy modalities and medications administered therewith may be given to respiratory therapy personnel, radiology instructions to radiology technicians, and physical therapy orders to physical therapists. All verbal and telephone orders shall be countersigned by the prescriber or his designee within 48 hours.

C. All medications shall be administered by a:

1. Medical doctor;
2. Osteopath;
3. Dentist;
4. Podiatrist;
5. Registered professional nurse;
6. Licensed practical nurse;
7. Registered pharmacist;
8. Respiratory therapy specialist (in a department under medical direction) for medications administered via respiratory therapy devices;
9. Student nurse under the direct supervision of a registered professional nurse who is the student's instructor; or

10. Respiratory therapy student under the direct supervision of a Respiratory Therapy Specialist who is the student's instructor.

The appropriate committee of the medical staff may, of course, establish more restrictive criteria regarding specific procedures, medications, groups and individuals.

D. Self-administration of medications by patients may be permitted only when specifically ordered by the physician in writing.

E. Medication errors and adverse drug reactions shall be reported immediately to the prescriber, supervising nurse and pharmacist and recorded in the patient's medical record.

F. Medications for each patient must be kept in the original container; transferring between containers is forbidden.

404.4 Isolation:

A. Patients and/or newborns shall be isolated and proper procedures shall be followed for the prevention of cross infection and for control of contagious diseases.

B. Any indication of infection shall be immediately called to the attention of the nursing supervisor and the physician in charge of the service.

404.5 Cleaning and Use of Equipment:

A. All equipment coming into contact with patients shall be adequately disinfected or sterilized after each use to maintain such equipment in a clean and sanitary condition, unless individual or disposable equipment is provided for each patient. Disposable materials and equipment shall be used by one patient only, and then disposed of in an acceptable manner.

B. Drinking water containers for patients may not be used if made of porous materials, such as Styrofoam, unless the containers have smooth liners that can be easily cleaned. Disposable containers must be replaced at least weekly for long term patients.

CHAPTER 5 - ACCOMMODATIONS FOR PATIENTS

SECTION 501. MAXIMUM NUMBER OF BEDS:

No facility shall have set up or in use at any time more beds than the number stated on the face of the license except in cases of justified emergencies.

A. The following categories of beds are not chargeable to the licensed number:

1. Labor room;
2. Newborn nursery;
3. Recovery room;
4. Emergency room treatment;
5. Classroom use only.

B. Neonatal special care beds will be shown on the face of the license in addition to the licensed bed capacity.

SECTION 502. LOCATION OF BEDS:

Beds shall not be placed in corridors, solaria or other locations not designed as patient room areas except in cases of justified emergencies.

SECTION 503. ROOM EQUIPMENT:

In addition to a bed with lockable casters, each patient shall be provided with at least one chair, a dresser or compartmented bedside table to accommodate the patient's personal possessions (built-in storage is permissible), a reading light and mattress with moisture-proof covering. Shock bed blocks or equivalent, such as pneumatic lifters for foot of bed and side rails, shall also be provided. All room equipment must be maintained in working condition. The above room furnishings do not apply in critical care areas.

SECTION 504. OXYGEN:

Hospitals shall provide oxygen for the treatment of patients. When oxygen is dispensed, administered or stored, adequate safety precautions against fire and other hazards shall be exercised. "No Smoking" signs shall be posted conspicuously and cylinders shall be properly secured in place.

SECTION 505. INTRAVENOUS FLUIDS:

Supportive equipment shall be provided for the administration of intravenous or

subcutaneous fluids.

SECTION 506. CUBICLE CURTAINS:

All semi-private and multi-bed rooms shall be equipped with cubicle curtains which will shield each patient completely. Curtains shall be at least flame resistant,

EXCEPTION: In psychiatric and in chemical and substance abuse treatment units, cubicle curtains and tracks are not required if they pose a threat to patient safety. However, other arrangements must be made to ensure privacy when needed or requested by a patient.

SECTION 507. MATTRESSES AND PILLOWS:

When purchasing new mattresses and pillows, resistance to fire, smoke development and toxicity of combustion gases must be prime factors in the selection.

CHAPTER 6 - GENERAL STANDARDS FOR SPECIALIZED DEPARTMENTS OR SERVICES

SECTION 601. MEDICAL RECORDS AND REPORTS:

601.1 Physician's Responsibility: It shall be the responsibility of each attending physician to complete and sign the medical record within a stipulated time after the discharge of the patient consistent with good medical practice. The use of rubber stamp signature is acceptable under the following strict conditions:

A. The physician whose signature the rubber stamp represents is the only one who has possession of the stamp and is the only one who uses it, and

B. The physician places in the administrative offices of the hospital a signed statement to the effect that he is the only one who has the stamp and is the only one who will use it. However, it must be emphasized that use of rubber stamp signatures is not permissible on orders for drugs listed as "controlled substances" under "Rules and Regulations Pertaining to Controlled Substances", Regulation 61-4 of the S.C. Code of Laws of 1976.

601.2 Organization: The responsibility for supervision, filing and indexing of medical records shall be assigned to a responsible employee of the hospital who has had training in this field.

601.3 Indexing: Medical records shall be properly indexed and filed for ready access by members of the staff.

601.4 Ownership: Records of patients are the property of the facility and must not be taken from the hospital property except by court order.

601.5 Contents:

A. Adequate and complete medical records shall be written for all patients admitted to the hospital and newborns delivered in the hospital. All notes shall be legibly written or typed and signed. Although use of initials in lieu of licensed nurses' signatures is not encouraged, initials will be accepted provided such initials can be readily identified within the medical record. A minimum medical record shall include the following information:

1. Admission Record: An admission record must be prepared for each patient and must contain the following information, when obtainable: Name; address, including county; occupation; age; date of birth; sex; marital status; religion; county of birth; father's name; mother's maiden name; husband's or wife's name; dates of military service; health insurance number; provisional diagnosis; case number; days of care; social security number; the name of the person providing information; name, address and telephone number of person or persons to be notified in the event of emergency; name and address of referring physician; name and address and telephone number of attending physician; date and hour of admission;

2. History and physical within 48 hours after admission;
3. Provisional or working diagnosis;
4. Pre-operative diagnosis;
5. Medical treatment;
6. Complete surgical record, if any, including technique of operation and findings, statement of tissue and organs removed and post-operative diagnosis;
7. Report of anesthesia;
8. Nurses' notes;
9. Progress notes;
10. Gross pathological findings and microscopic;
11. Temperature chart, including pulse and respiration;
12. Medication Administration Record or similar document for recording of medications, treatments and other pertinent data. Nurses shall sign this record after each medication administered or treatment rendered;
13. Final diagnosis and discharge summary;
14. Date and hour of discharge summary;
15. In case of death, cause and autopsy findings, if autopsy is performed;
16. Special examinations, if any, e.g., consultations, clinical laboratory, x-ray and other examinations.

B. Newborn Records: Newborn records should include the following:

1. History of hereditary conditions in mother's and/or father's family;
2. First day of the last menstrual period (L.M.P.) and estimated day of confinement (E.D.C.);
3. Mother's blood group and RH type -- evidence of sensitization and/or immunization (such as, administration of anti-D hyperimmune globulin);
4. Serological test for syphilis (including dates performed);

5. Number, duration and outcome of previous pregnancies, with dates;
6. Maternal disease (e.g., diabetes, hypertension, pre-eclampsia, infections);
7. Drugs taken during pregnancy, labor and delivery;
8. Results of measurements of fetal maturity and well-being (e.g., lung maturity and ultrasonography);
9. Duration of ruptured membranes and labor, including length of second state;
10. Method of delivery, including indications for operative or instrumental interference;
11. Complications of labor and delivery (e.g., hemorrhage or evidence of fetal distress), including a representative strip of the fetal ECG if recorded;
12. Description of placenta at delivery, including number of umbilical vessels;
13. Estimated amount and description of amniotic fluid;
14. Apgar scores at one and five minutes of age. Description of resuscitations, if required, detailed description of abnormalities and problems occurring from birth until transfer to the special nursery or the referral facility.
15. Test results and date specimen was collected for PKU and hypothyroid newborn screening test. (Exempt only when parents object because of religious convictions; then file copy of executed "Statement of Religious Objection Form", DHEC #1804 with newborn record.)

601.6 Orders for Medication and Treatment: All medical records shall contain the orders for medication and treatment written in ink and signed and dated by the prescriber or his designee. All orders, including verbal orders, shall be properly recorded in the medical record and dated and signed by the prescriber or designee within 48 hours.

601.7 Storage and Microfilming:

A. Provisions shall be made by the hospital for the storage of medical records in an environment which will prevent unauthorized access and deterioration. The records shall be treated as confidential and shall not be disposed of under 10 years. Records may be destroyed after 10 years provided that:

1. Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute;

2. The hospital retains an index, register, or summary cards providing such basic information as dates of admission and discharge, name of responsible physician, and record of diagnoses and operations for all records so destroyed.

B. Facilities that microfilm before 10 years have expired must film the entire record.

C. In the event of change of ownership, all medical records shall be transferred to the new owners.

D. Prior to the closing of a hospital for any reason, the facility shall arrange for preservation of records to insure compliance with these regulations. The facility shall notify the Department, in writing, describing these arrangements.

601.8 Information to be Provided to Other Health Care Providers: In order to contribute to the continuity of quality of care, procedures must be established and implemented to provide discharge summaries and/or other appropriate information to health care providers to whom patients are discharged, transferred or referred.

SECTION 602. LABORATORY:

602.1 Organization: The laboratory shall be under the supervision of a physician, preferably one who has had special training in clinical laboratory procedures. The laboratory personnel shall be qualified by education, training, and experience for the type of services rendered.

602.2 Reports and Procedures:

A. A written and signed report of each laboratory test and examination shall be made a part of the patient's record. Although use of initials in lieu of signatures is discouraged, initials will be accepted provided such initials can be identified readily from a roster of individual initials with signature on permanent file.

B. All procedures performed shall contain appropriate controls to insure accuracy of results.

602.3 Facilities:

A. Laboratory facilities, equipment and supplies must be provided in keeping with services rendered by the hospital; this should include blood and plasma at all times.

B. The governing authority shall designate the pathologist or other physician as physician-in-charge of the blood bank service.

C. Hospitals which provide for procurement, storage and transfusion of blood shall have acceptable facilities, including a refrigerator, for whole blood. The temperature shall be maintained at 2 to 6 degrees C. or 36 to 43 degrees F., and no foods may be kept in this

refrigerator. Standards of the American Association of Blood Banks, as outlined in the most current edition of Standards for a Blood Transfusion Service, will be used as a guide for licensing purposes.

D. Records shall be kept on file indicating the receipt and disposition of all blood handled. Particular care shall be taken to ascertain that blood administered has not exceeded its expiration date.

E. The hospital should make adequate arrangements to secure on short notice all necessary supplies of whole blood, typed and crossmatched as required, for emergencies.

F. A bacteriological hood shall be provided in the hospital laboratory for procedures involving patients with infectious diseases.

NOTE: Hospitals constructed prior to April 23, 1979, will not be required, but will be encouraged, to install equipment named in F immediately above if the individual situation warrants, based upon the needs as determined by the medical staff and approved by the hospital's governing body.

SECTION 603. RADIOLOGY:

603.1 Organization: The radiology department shall have a physician in charge. The x-ray personnel shall be qualified by education, training, and experience for the type of service rendered.

603.2 Reports: A written, signed report on each x-ray and therapy treatment shall be made a part of the patient's record; a duplicate copy of the report shall be kept on file in the x-ray department. Each request for x-ray examination shall include a concise statement of the reason for the examination.

603.3 Filing of X-ray Film: The length of time that x-ray film shall be kept on file shall be determined by the individual hospital. For its own protection, every hospital should consult with its legal counsel before selling or disposing of film.

603.4 Protection: Patients and employees shall be provided protection from radiation in accordance with current practices outlined by the Department.

SECTION 604. PHARMACEUTICAL SERVICES:

604.1 A. All facilities providing pharmaceutical services shall provide such services under the direction of a registered pharmacist currently licensed in S.C. Pharmaceutical services shall be provided in accordance with accepted professional principles and appropriate federal, state and local laws and regulations.

B. Facilities which maintain stocks of drugs and biologicals to be dispensed to outpatients shall obtain and maintain a current valid Pharmacy Permit from the State Board

of Pharmaceutical Examiners.

604.2 Personnel - Supervision:

A. The pharmaceutical service shall be directed by a registered pharmacist either on a full or part-time basis. The pharmacist directing the pharmaceutical services is responsible to the administration of the hospital for developing, supervising and coordinating all of the activities of the pharmacy department, which should include, but are not limited to, the following:

1. Dispensing medications in such form that will minimize additional preparation before administering to the patient;
2. Monitoring all medication orders to ensure that clinically significant chemical and therapeutic incompatibilities within the patient's drug regimens are reported to the prescribing physician;
3. Providing education programs for the facility's personnel and counseling patients regarding their medications, including their safe use;
4. Providing a method by which medications can be obtained during the absence of a pharmacist in the facility in such a manner that will minimize the potential for medication error and assure control and accountability of any drugs. A pharmacist shall be available on an on-call basis at all times.
5. Assisting in the formulation of professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures relating to drugs in the facility;
6. Monthly review of drugs and drug records in all locations in which drugs are stored, including, but not limited to, nursing stations, emergency rooms, outpatient departments, operating suites, emergency kits, etc.

B. The pharmacist shall be assisted by an adequate number of additional registered pharmacists and such other personnel as the activities of the pharmacy may require to insure quality pharmaceutical services. Supportive personnel shall have necessary training and experience to perform assigned duties.

604.3 Drug Distribution and Control: The pharmaceutical service shall have written policies and procedures for control and accountability, drug distribution, and assurance of quality of all drugs and biological products throughout the hospital.

A. The pharmacy service shall establish and maintain a satisfactory system of records and bookkeeping in accordance with the policies of the hospital and in compliance with all state and federal regulations.

B. A record of the stock and distribution of all controlled substances in Schedule II shall be maintained in such a manner that the disposition of any particular item may be readily traced. All such records shall be maintained in compliance with the requirements of the federal and state Controlled Substances Acts.

C. Records on drugs dispensed to outpatients shall be maintained in compliance with the laws and regulations applicable to retail pharmacies.

D. Investigational Drugs: Records for investigational drugs shall be maintained in the pharmacy in compliance with the Federal Food and Cosmetic Act Regulations.

604.4 Physical Facilities and Storage: Facilities shall be provided for the storage, safeguarding, preparation and dispensing of drugs.

A. Drugs must be issued to floor units in accordance with approved policies and procedures.

B. Drug storage on the nursing units shall be reviewed monthly by the pharmacist or a properly trained individual designated by the pharmacist; a record of each review shall be maintained. All floor stocks shall be properly controlled. Medications requiring refrigeration shall be kept in a locked refrigerator used exclusively for medications, or in a separate locked box within a multi-use refrigerator at or near the nurses' station. Refrigerators shall be provided with a thermometer accurate to ± 2 degrees F.

C. Adequate space shall be provided for all pharmacy operations. Drugs shall be stored in satisfactory locations which have been provided with proper lighting, ventilation and temperature controls, including a reliable thermometer accurate to ± 2 degrees F. in each refrigerator.

D. Adequate equipment shall be provided for the compounding, labeling and distribution of drugs in compliance with the laws and regulations governing the practice of pharmacy in S.C.

E. Special locked and ventilated storage space shall be provided to meet the legal requirements for storage of narcotics, alcohol, and other prescription drugs. Alcohol storage shall be ventilated.

F. The keys to the pharmacy shall be in the possession of personnel approved by the hospital administration.

G. Medications "For External Use Only" and poisons shall be kept in a locked room or cabinet separate from other medications. Topical ointments, eye drops and similar preparations are not included in this requirement.

H. Emergency boxes, kits or (crash) carts shall be sealed and, when not in actual use, stored either in a secured area or under visual control from the nurses' station. The

contents of these containers shall be approved by the appropriate committee of the facility. An inventory list of the contents shall be maintained in or on the container.

604.5 Labeling of Medications:

A. Any medication dispensed to inpatients shall be identified with its name and strength labeled on the container in which it is dispensed or on each single unit package. The name of the patient and any identifying number shall be labeled on the container. The prescribing physician's name and directions for use shall be on the container if it is not communicated in another effective manner.

Exceptions to the above must be approved by the Department.

B. Labeling of drugs dispensed to outpatients shall be in compliance with laws and regulations applicable to retail pharmacies.

C. If drugs are issued to nursing units or other locations as floor stock, the label must include the name and strength of the drug, expiration date, lot or control number and any precautionary labels as appropriate.

D. Medication containers having soiled, damaged, incomplete, illegible or makeshift labels shall be returned to the pharmacy or drug room for relabeling or disposal. Containers having no labels are prohibited and contents shall be destroyed.

604.6 Discontinued or Outdated Medications: Outdated or discontinued medications shall be returned to the pharmacy for proper disposition in accordance with good pharmaceutical practice and facility policy. Medications that have been subjected to contamination shall not be redispensed.

604.7 Disposition of Medications on Discharge: Unused medications may be turned over to the patient for whom prescribed on discharge only on the written order of the attending physician. Such medications must be returned to the pharmacy to be labeled in accordance with Section 604.5.B before release.

604.8 Stop Orders: The medical staff shall establish a written policy that certain medications not specifically prescribed as to time or number of doses will be automatically stopped after a time limit set by the medical staff.

604.9 General:

A. Self-administration of medications by patients may be permitted only when specifically ordered by the physician in writing. Self-administered medications shall be recorded on the medication administration record by the appropriate licensed personnel.

B. Up-to-date reference materials shall be provided in order to furnish the medical and nursing staff with adequate information concerning the drugs.

C. Nothing in these regulations shall be construed to interfere with any licensed practitioner of medicine in the compounding of his own prescriptions and dispensing to his own patients, providing it is allowed by hospital bylaws.

SECTION 605. CENTRAL SUPPLY

605.1 Personnel:

A. The department head shall be qualified for the position by education, training and experience.

B. The number of supervisory and other personnel shall be related to the scope of the services provided.

605.2 Policies and Procedures: There shall be written policies and procedures for the decontamination and sterilization activities performed in central supply and elsewhere in the hospital. These policies and procedures shall relate, but are not limited to the following:

1. The use of sterilization process monitors, including temperature and pressure recordings, and the use and frequency of appropriate chemical indicator and bacteriological spore tests for all sterilizers.

2. Designation of the shelf life for each hospital-wrapped and hospital-sterilized medical item and, to the maximum degree possible, for each commercially prepared item, by a specific expiration date that sets a limit on the number of days an item will be considered safe for use. When possible, load control numbers shall be used to designate the sterilization equipment used for each item, including the sterilization date and cycle.

605.3 Controls: A recognized method of checking sterilizer performance shall be used. A chemical indicator of some type should be included in the largest package of each load. Biological indicators (live bacterial spores) should be included in all steam and hot air sterilizers at least once per week or more often depending upon the degree of sterilizer usage. Gas sterilizers should employ such indicators on at least a weekly basis and preferably on a daily basis. Further, the gas sterilization of implants, prosthetic devices, etc., should be accompanied by a biological monitor in each load. Monthly checks shall be made to ensure the above, and a written report retained.

605.4 Storage: Adequate precautions shall be taken to ensure that sterile supplies and equipment are not mixed with unsterile material. Suitable space shall be provided for keeping equipment and supplies in a clean, convenient and orderly manner.

605.5 Containers and Packages: All packaged supplies and containers for solutions, drugs, medicated supplies, etc., shall be labeled so as to remain plainly legible before and after sterilization. Labels shall include at least the expiration date of the contents.

605.6 Outdated Supplies: Outdated medical supplies, solutions, etc., shall be returned to central supply for resterilization or disposal.

SECTION 606. SURGERY

606.1 Organization:

A. Consulting Staff: Hospitals providing surgery should have available consulting physicians or a committee of consulting physicians.

B. Department Head: The surgical service shall be under the supervision of a member of the active staff of physicians.

C. Nursing Personnel: The operating suite shall be under the supervision of a registered nurse.

606.2 Facilities: The operating rooms shall be separated from non-sterile areas and shall be located so as not to be used as a passageway between, or subject to contamination from, other parts of the hospital.

606.3 Equipment:

A. Hospitals shall provide surgical equipment and instruments in good repair to assure safe and aseptic treatment. Any indication of contamination shall be immediately called to the attention of the nursing supervisor and the physician in charge of the service.

B. Functional equipment and material shall be available for life support devices and administering medical gases.

1. Ultrasound and ECHO cardiogram are available within one hour (30 minutes is recommended) on a 24-hour basis.

2. The following clinical laboratory services must be available 24 hours a day:

- a. Chromosome analysis;
- b. Viral culture.

SECTION 607. PERINATAL ORGANIZATION

A. Each hospital providing perinatal services shall be designated as a Level I, II, II Enhanced (IIE), III perinatal hospital, or regional perinatal center (RPC) by the Department, and shall request such designation by letter to the Department. The Department shall include such designation on the face of the license when the requesting hospital meets the requirements specified below. Such determination shall be made by the Department based upon a hospital's ability to meet regulatory requirements to be determined by a special

inspection by the Department following the initial request for designation and as an integral part of subsequent license renewal procedures.

B. Each Level I, II, IIE, and III hospital shall maintain and document a relationship with its designated RPC for consultation, transport and continuing education. All patients shall be transferred to the appropriate RPC when medically appropriate, if beds are available. This agreement/relationship shall include the ability to share data, as appropriate, related to these functions.

607.1. Intrapartum: Labor and Delivery Process: Labor and delivery shall occur in a hospital capable of meeting the expected needs of both the mother and the neonate. Ongoing risk assessment shall occur to determine the appropriate level of care.

607.2. Designation of Inpatient Perinatal Care Services

A. Community Perinatal Center (Level I). Provides services for uncomplicated deliveries and normal neonates. The hospital shall have the capability to manage normal pregnant women and uncomplicated labor and delivery of neonates who are at least 36 weeks of gestation with an anticipated birth weight of greater than 2000 grams. When it is anticipated or determined that these criteria will not be or have not been met, consultation and a plan of care shall be initiated and mutually agreed upon with the RPC. Hospitals must be able to manage a perinatal patient with acute or potentially life-threatening problems while preparing for immediate transfer to a higher level hospital. Management shall include emergency resuscitation and/or stabilization for both maternal and neonatal patients in preparation for transfer/transport for more specialized services. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals.

B. Specialty Perinatal Center (Level II). In addition to Level I requirements, provides services for both normal and selected high-risk obstetrical and neonatal patients. This level of neonatal care includes the management of neonates who are at least 32 weeks of gestation with an anticipated birth weight of at least 1500 grams. A board-eligible pediatrician shall be in the hospital or on site within 30 minutes, 24 hours a day. The hospital shall have at least a written consultative agreement with a board-eligible neonatologist. Neonates shall be without acute distress or complex management requirements and shall not be in need of ventilatory support for more than six cumulative hours. Neonates shall not require high-frequency ventilation support. When it is anticipated or determined that these criteria will not be or have not been met, a plan of care will be developed in consultation with the RPC and documented in the patient's medical record. These hospitals shall manage no less than an average of 500 deliveries annually, calculated over the previous three years. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. A Level II hospital shall not admit outborn neonates into its nursery without prior concurrence with the RPC. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals.

C. Enhanced Perinatal Center (Level IIE). In addition to Level II requirements, provides

services for both normal and selected high-risk obstetrical and neonatal patients. Level IIE hospitals may be located only in areas of the state which are no closer than 60 miles from a S.C. Regional Perinatal Center. This level of neonatal care includes the management of neonates who are at least 30 weeks of gestation with an anticipated birth weight of at least 1250 grams, as determined by estimations based upon best professional judgement, ultrasound, and/or other available medical technology and instruments. A board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. Neonates shall not be in need of ventilatory support for more than 24 cumulative hours. When it is anticipated or determined that any of the preceding criteria relating to gestation, weight and length of ventilatory support will not be or have not been met, the neonate may remain at the Level IIE facility, pursuant to a plan of care developed in consultation with, and agreement to by, the RPC. Such plan of care shall be documented in the patient's medical record. Neonates shall not require high-frequency ventilation support. These hospitals shall manage no less than an average of 1200 deliveries annually, calculated over the previous three years. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. A Level IIE hospital shall not admit outborn neonates into its nursery without prior concurrence with the RPC. Hospitals at this level shall not provide care or services which are designated only for higher level hospitals.

D. Subspecialty Perinatal Center (Level III). In addition to Level IIE requirements, provides all aspects of perinatal care, including intensive care and a range of continuously available subspecialty consultation as recommended in the fourth edition of the *Guidelines for Perinatal Care* (GPC) by the American Academy of Pediatrics (AAP) and The American College of Obstetricians and Gynecologists. A board-eligible neonatologist shall be in the hospital or on site within 30 minutes, 24 hours a day. A board-certified maternal-fetal medicine specialist (perinatologist) shall be available for supervision and consultation, 24 hours a day. In addition to the Level II and IIE capabilities, Level III hospitals shall have the staffing and technical capability to manage high-risk obstetric and complex neonatal patients, including neonates requiring prolonged ventilatory support, surgical intervention, or 24-hour availability of multispecialty management. Hospitals with Level III designation shall manage no less than an average of 1500 deliveries annually, calculated over the previous three years, or at least an average of 125 neonate admissions who weigh less than 1500 grams each, require ventilatory support, or require surgery. This calculation shall include the number of maternal transfers made prior to delivery to higher level perinatal hospitals. Hospitals at this level shall not provide additional care or services designated only for RPC's.

E. Regional Perinatal Center (RPC). In addition to the Level III requirements for management of high-risk obstetric and complex neonatal conditions, the RPC shall provide consultative, outreach, and support services to Level I, II, IIE and III hospitals in the region. The RPC shall manage no less than an average of 2000 deliveries annually, calculated over the previous three years, or at least an average of 250 neonate admissions who weigh less than 1500 grams each, require ventilatory support, or require surgery. Personnel qualified to manage obstetric or neonatal emergencies shall be in-house. A board-certified maternal-fetal medicine specialist (perinatologist) shall be in the hospital or on site within 30 minutes for supervision and consultation, 24 hours a day. The RPC shall participate in

residency programs for obstetrics, pediatrics, and/or family practice. Continuing education and outreach education programs shall be available to all referring hospitals, and physician-to-physician consultation shall be available 24 hours a day. The RPC shall provide a perinatal transport system that operates 24 hours a day, seven days a week, and return transports neonates to lower level perinatal hospitals when the neonates' condition and care requirements are within the capability of those hospitals.

SECTION 608. PERSONNEL

608.1. Support Services: Detailed components of support services and medical, nursing and ancillary staffing for each level shall meet the recommendations outlined in the fourth edition of the *Guidelines for Perinatal Care*.

608.2. Medical Specialists: The following medical specialists and subspecialists shall have medical staff credentials and/or written consultative agreements as follows:

A. Level I:

1. Membership: Physician designated as physician-in-charge of obstetric services, physician designated for supervision of newborn care, anesthesia personnel with credentials to administer obstetric anesthesia available within 30 minutes, 24-hours a day, one person capable of initiating neonatal resuscitation available at every delivery.

2. Consultation: Obstetrician, pediatrician, surgeon.

B. Level II, in addition to Level I requirements:

1. Membership: General surgeon, pathologist, radiologist, obstetrician, pediatrician, and anesthesiologist;

2. Consultation: Maternal-fetal medicine specialist, neonatologist, and pediatric surgeon.

C. Level IIE, in addition to Level II requirements:

1. Membership: Board-certified neonatologist designated as physician-in-charge of neonatal services, cardiologist, urologist, neurosurgeon, and hematologist;

2. Consultation: Cardiac surgeon, medical geneticist, pediatric cardiologist, pediatric radiologist, obstetrician or radiologist with special interest and competence in maternal disease and its complications, endocrinologist, pediatric neurologist, and pulmonologist.

D. Level III and RPC, in addition to Level IIE requirements:

1. Membership: Maternal-fetal medicine specialist, obstetrician or radiologist with special interest and competence in maternal disease and its complications, pediatric

radiologist, anesthesiologist with perinatal training and/or experience; pathologists with special competence in placental, fetal, and neonatal disease, and pediatric surgeon;

2. Consultation: Pediatric subspecialists in hematology, medical genetics, endocrinology, nephrology, gastroenterology, infectious diseases, pulmonology, immunology, and pharmacology. Pediatric surgical subspecialists, to include cardiovascular, neurosurgery, orthopedics, ophthalmology, urology and otolaryngology.

608.3. Neonatal Intensive Care Nurse Staffing: Neonatal intensive care nurse staffing is required if any of the following conditions exist:

A. Any advanced support therapy, e.g., extracorporeal membrane oxygenation, nitric oxide, high frequency ventilation, peritoneal dialysis;

B. Acute pre- or post-operative surgical conditions, except for minor surgical procedures such as inguinal hernia repair;

C. Ventilatory support required for more than six cumulative hours duration (with the exception of do-not-resuscitate situations and chronic ventilator-dependent conditions);

D. Less than 32 weeks of gestation and less than 1500 grams on the first day of life;

E. Chest tubes required;

F. Cardio-pulmonary resuscitation required in the previous 24 hours;

G. Vital signs required every hour or more frequently;

H. Three or more intravenous sites required;

I. Pressor agent (excluding initial stabilization) or inotropic support required, e.g., dopamine (doses for renal perfusion maintenance excluded);

J. Complex diagnostic/assessment support required;

K. Evidence of seizure activity/unstable neurologic status.

SECTION 609. GENERAL FACILITY AND CARE REQUIREMENTS

609.1. Physical Facilities: Environment, equipment, supplies, and procedures utilized in the care of perinatal patients shall meet the recommendations outlined in the fourth edition of the GPC.

609.2. Obstetrical Care: In each hospital providing obstetrical services, written policies and procedures shall be established and implemented through cooperative efforts of the medical and nursing staffs. These policies and procedures shall outline the process,

providers, and methods of providing risk-appropriate care to the obstetrical patient, and shall include, but not be limited to:

- A. Admission criteria and documentation;
- B. Preterm labor;
- C. Maternal transfer to another hospital;
- D. Induction and augmentation;
- E. Analgesia and anesthesia;
- F. Labor process;
- G. Capability to perform cesarean delivery within 30 minutes of the decision to do so;
- H. Immediate neonatal care/resuscitation;
- I. Recovery room care;
- J. Postpartum care.

609.3. Neonatal Care: Specific policies and procedures for the care of the neonate shall follow the recommendations outlined in the fourth edition of the GPC.

609.4. Neonatal Resuscitation:

A. Personnel, equipment, supplies, and medications as recommended by the 2000 edition of the American Heart Association and *AAP Textbook of Neonatal Resuscitation* shall be readily available in every hospital providing perinatal services.

B. In order to meet the potential need for resuscitation of every neonate, at least one person who has a current provider-designation, as defined by completion of the AAP Neonatal Resuscitation Program, shall be on site.

C. Personnel trained and qualified to perform neonatal resuscitation must be immediately available and not responding from an area removed from the delivery or nursery area.

D. Equipment, supplies, and medications for neonatal resuscitation must be immediately available to the delivery and nursery areas at all times.

609.5. Inter-hospital Care of the Perinatal Patient (Transport):

- A. Each hospital providing perinatal services shall establish and implement a written

plan which outlines the process, providers, and methods of providing risk-appropriate stabilization and transport of any high-risk perinatal patient requiring specialized services. This plan shall be updated in conjunction with the designated RPC on an annual basis, and shall include, but not be limited to, procedures outlining:

1. Communication between referring hospitals and the RPC, transport teams and medical control, and perinatal providers and families;
2. Indications for both acute phase and return transport between perinatal hospitals, to include essential contact persons and telephone numbers for referral and transport;
3. A list of all medical record copies and additional materials to accompany each patient in transport.

B. Equipment, supplies, and procedures used in preparation and support of transport of maternal patients shall be based upon the fourth edition of the GPC. Equipment, supplies, and procedures used in the transport of a neonate shall be based upon the 1999 edition of the *AAP Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients*.

SECTION 610. EVALUATION OF PERINATAL CARE

A. Review of maternal and neonate mortality and morbidity shall be conducted at least every three months by the medical staff or designated committee, regardless of the size or designation of the perinatal service. A perinatal mortality and morbidity review committee composed of representatives from the pediatric, obstetrical, and nursing staffs, with additional participation from other professionals, depending upon the cases to be reviewed, shall be established at Levels II, IIE, and III, and RPC's.

B. In all perinatal centers, selected case reviews shall include, but not be limited to:

1. Analysis of total perinatal mortality with identification of deaths attributable to various categories of complication;
2. Analysis of perinatal morbidity and related factors.

C. Each hospital providing perinatal services shall review all live births or fetal/neonatal deaths in which the neonate weighed less than 1500 grams, utilizing the Department's *Very Low Birthweight Self-monitoring Tool*. Each completed self-monitoring DHEC form shall be retained by the facility and a copy made available to the Department as specified in the self-monitoring tool.

D. Each event shall be evaluated for potential opportunities for intervention with the intervention and follow-up described, if applicable. Written minutes of committee meetings shall be maintained.

E. Each perinatal center shall annually review and document the findings from these

case reviews with its designated RPC.

SECTION 611. ANESTHESIA:

611.1 Administration: Anesthesia shall be administered only by a CRNA, anesthesiologist or a physician anesthesiologist. After the administration of a general anesthetic, patients shall be constantly attended by nursing personnel until they have regained full consciousness, or until the effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid when needed.

611.2 Physical Examination: Operations under a general anesthetic shall not be performed nor a general anesthetic given until the patient has had a physical examination except in emergency situations. When less than a complete physical examination is acceptable, the results of these examinations shall be entered in the patient's record.

611.3 Equipment: Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient. The device shall emit an audible and/or visual alarm should the proportion of oxygen fall below a safe level.

SECTION 612. OUTPATIENT DEPARTMENT:

612.1 Organization: If the facility provides outpatient services, a physician shall be in charge of the overall service.

612.2 Outpatient Medical Records: Complete records shall be kept on all outpatients and shall be completed immediately after treatment is rendered. These records shall contain sufficient identification data, a description of what was done and/or prescribed for the patient and must be signed by the attending physician. When a patient is admitted as an inpatient, all of his outpatient records shall be made a part of his permanent medical record. Records of patients are the property of the facility and must not be taken from the hospital property except by court order. These records shall be maintained and disposed of as specified in Section 601.7.

612.3 Facilities: The outpatient department shall be in a location that is easily accessible for all patients and shall have easy access to all necessary hospital services, including clinical laboratory, x-ray and other diagnostic and therapeutic services, utility and sterilization facilities. Adequate toilet facilities, waiting, dressing, examining and treatment rooms shall be provided.

SECTION 613. EMERGENCY SERVICES:

613.1 Each hospital shall provide emergency services which include life-saving procedures when life is in jeopardy. Policies and procedures governing the acceptance and care of emergency patients shall be established. An appropriate record shall be maintained on each person who presents for emergency services.

A. Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer of the critically ill or injured to other hospitals. A minimum capacity shall be established and equipment provided to perform procedures such as hemostasis, therapy of traumatic shock, maintenance of airway and cardiopulmonary resuscitation.

B. Basic services, such as x-ray and routine laboratory services, shall be maintained and personnel available for call.

C. A licensed physician shall be available and on call at all times. A registered nurse and ancillary personnel trained in emergency procedures shall be on duty within the hospital who are available 24 hours a day subject to call to assist in providing emergency services.

613.2 No person, regardless of his ability to pay or county of residence, may be denied emergency care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's staff determines that the person is in need of emergency care.

A. For the purposes of this section, "emergency care" means treatment which is usually and customarily available at the respective hospital and that must be provided immediately to sustain a person's life, to prevent serious permanent disfigurement or loss or impairment of the function of a bodily member or organ, or to provide for the care of a woman in active labor and the infant.

B. If a patient presents in labor, she should be delivered in the hospital to which she has come if appropriate delivery facilities exist, If she is a "high risk" patient or an adverse outcome is expected for the baby if delivered there, e.g., less than 34 weeks gestation, she should be transported to a hospital with appropriate capabilities unless delivery is imminent or unless the hospital has such capabilities.

C. If the care required for any patient is not available at the facility, arrangements must be made for transfer to a more appropriate facility. Prior to the transfer of a patient to another hospital, the receiving hospital shall be notified of the impending transfer.

D. In addition to or in lieu of any action taken by the Department affecting the license of any hospital, when it is established that any officer, employee, or member of the hospital medical staff has recklessly violated the provisions of this section, the Department may require the hospital to pay a civil penalty of up to ten thousand dollars.

613.3 A poison control chart shall be maintained in the emergency room with communications access to a Poison Control Center for consultation.

613.4 The emergency service entrance shall be separated from the main entrance, well marked and illuminated, easily accessible from the street and sufficiently covered or enclosed to protect ambulance patients from the elements during the unloading process.

613.5 Space for stretchers and wheelchairs should be located immediately adjacent to the entrance. Stretchers should be sufficiently sturdy to serve as examining tables and x-ray permeable.

613.6 **EXCEPTION:** In those instances wherein a specific hospital has been designated to provide emergency services for a political or other subdivision through mutual planning efforts of all the hospitals located in this subdivision, or otherwise determined, such designation obviates the necessity for the remaining hospitals to provide general emergency services.

SECTION 614. DENTAL SURGERY:

614.1 Organization: If hospitals provide dental services, a qualified practitioner of dentistry shall be in charge of the dental services and shall be a member of the medical staff.

614.2 Facilities: For hospitals providing dental services, equipment shall be provided for the diagnosis and treatment of diseases of the oral cavity.

SECTION 615. PHYSICAL THERAPY:

If offered as a service of the hospital, physical therapy shall be on orders of a physician and administered by or under supervision of a registered physical therapist. Adequate space and equipment shall be provided.

SECTION 616. OCCUPATIONAL THERAPY:

If offered as a service of the hospital, occupational therapy shall be on orders of a physician and administered by or under supervision of an occupational therapist. Adequate space and equipment shall be provided.

SECTION 617. PSYCHIATRIC SERVICE:

A. A physician, preferably a board-certified psychiatrist, should be designated as physician-in-charge (or chief of the psychiatric service). A designated physician who is experienced in the practice of psychiatry should be on call at all times.

B. A registered nurse who has had at least two years training and/or experience in psychiatric nursing shall be responsible for the nursing care of psychiatric patients. At least one registered nurse shall be on duty in each nursing unit at all times.

SECTION 618. CHEMICAL AND SUBSTANCE ABUSE TREATMENT SERVICE:

A. A physician, who is experienced in the treatment of chemical and substance abuse, shall be designated as physician-in-charge of this service. Such a physician shall also be

on call at all times.

B. A registered nurse who has had at least two years training and/or experience in chemical and substance abuse care shall be responsible for the nursing care of this service. At least one registered nurse shall be on duty in each nursing unit at all times who has demonstrable training in chemical and substance abuse treatment. Relevant content of this training shall include physical and psychological assessment, psychopharmacology, basic counseling and intervention techniques, and the role of self-help groups in the recovery process. The training may be received through on-the-job training, specialized workshops, or classroom experience.

SECTION 619. PEDIATRICS:

A. Organization: Pediatric services, if provided, shall be under the supervision of a registered nurse.

B. Facilities: Pediatric services shall have separate facilities for the care of children. Facilities and procedures shall be provided for isolation of children having contagious infections or communicable diseases.

C. Pediatric Nursery: Pediatric nurseries shall provide at least 40 square feet per bassinet or 80 square feet per crib.

CHAPTER 7 - VITAL STATISTICS

SECTION 701. GENERAL:

Hospitals must comply fully with the “Rules and Regulations of the S.C. Department of Health and Environmental Control Relating to Vital Statistics.”

SECTION 702. BIRTH CERTIFICATES:

702.1 Newborn Inpatients: A licensee shall have the name of the physician, nursery midwife or person attending typed in the appropriate section of the birth certificate, along with the signature of the Medical Records Administrator or clerk affixed on births occurring in a hospital where a physician does not sign the certificate within the prescribed 10 days.

702.2 Newborn Outpatients: A licensee shall be responsible for filing a birth certificate for newborn outpatients brought to the emergency room, delivered either at home or enroute to the hospital. When all of the information is not available to complete the birth certificate, a statement by the hospital containing the name and address of the person who brought the infant to the hospital for treatment should be attached to the incomplete certificate.

SECTION 703. DEATH CERTIFICATES:

Death certificates are the responsibility of the mortician who initially attends the deceased.

CHAPTER 8 - FOOD SERVICE

SECTION 801. APPROVAL:

The kitchen and/or other food preparation centers must be inspected and approved by the Department pursuant to "Rules and Regulations Governing Food Service Establishments."

SECTION 802. SERVICES:

All facilities shall provide dietary services to meet the daily dietary needs of patients in accordance with written dietary policies and procedures.

SECTION 803. SUPERVISION:

The dietary services shall be under the direction of a dietitian or qualified food service supervisor who has a written agreement for consultation services by a dietitian. These services shall be organized with established lines of accountability and clearly defined job assignments. A qualified food service supervisor shall be a person who:

1. Is a graduate of a dietetic technician or dietetic assistant training program approved by the American Dietetic Association; or
2. Is a graduate of a State-approved course; or
3. Has training and experience in food service supervision and management equivalent in content to the programs in paragraph 1 or 2 above.

SECTION 804. PERSONNEL:

A. Persons engaged in the preparation and serving of food shall meet all requirements of the Department regarding food service personnel and shall be trained to perform assigned duties.

B. Trained personnel shall be provided to plan, prepare and serve the proper diets to patients.

C. The food service supervisor shall be responsible for supervising food service personnel, the preparation and serving of the food, and the maintenance of proper records. When the food service supervisor is not on duty, a responsible person shall be assigned to assume his/her job functions.

D. Work assignments and duty schedules shall be posted and kept current.

E. No person, infected with or a carrier of a communicable disease, or while having boils, open or infected skin lesions, or an acute respiratory infection, shall work in any area of food preparation and service.

F. Employees shall wear clean garments, maintain a high degree of cleanliness, wear small-mesh hair nets, and conform to hygienic practices while on duty. They shall wash their hands thoroughly in an approved hand washing lavatory before starting work, and as often as may be necessary to remove soil and contamination. No employee shall resume work after visiting the toilet room without first washing his hands.

SECTION 805. DIETS:

Diets shall be prepared in conformance with physicians' orders. A current diet manual shall be readily available to attending physicians, dietary service personnel and nursing personnel.

A. Diets shall be prescribed, dated and signed by the physician.

B. Facilities with patients in need of special or therapeutic diets shall provide for such diets.

C. Notations shall be made in the medical record of diet served, counseling or instructions given, and patient's tolerance of the diet.

D. Diets shall be planned, written, prepared and served with consultation from a dietitian.

E. Persons responsible for diets shall have sufficient knowledge of food values in order to make substitutions when necessary. All substitutions made on the master menu shall be recorded in writing.

SECTION 806. PLANNING OF MENUS AND FOOD SUPPLIES:

A. Menus shall be planned and written at least two weeks in advance and dated as served. The current week's menus, including routine and special diets and any substitutions or changes made, shall be posted in one or more conspicuous places in the dietary department.

B. Records of menus as served shall be filed and maintained for at least 30 days.

C. Records of food and supplies purchased shall be kept on file.

SECTION 807. PREPARATION AND SERVING OF FOOD:

A. Food shall be prepared by methods that conserve the nutritive value, flavor and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the nutritional needs of the patients.

B. A file of tested recipes, adjusted to appropriate yield, shall correspond to items on

the posted menus.

C. Food shall be cut, chopped, ground or blended to meet individual needs.

D. Dietary personnel will have the responsibility of accompanying the food cart to the floor when necessary to complete tray assembly. Facilities with automated food distribution systems in operation are not required to have dietary personnel accompanying the cart. Each facility shall designate who will be responsible for distribution of trays, feeding of patients, and collection of soiled trays. If personnel other than nursing staff are assigned these tasks, approval must be given by the appropriate committee of the medical staff. A copy of the minutes of the pertinent committee meeting shall be forwarded to the Department within 15 days of such approval.

SECTION 808. DIETARY AND FOOD SANITATION:

A. Sanitary conditions shall be maintained in all aspects of the storage, preparation and distribution of food.

B. The facility shall be in compliance with local health codes and the "Rules and Regulations Governing Food Service Establishments in South Carolina."

C. Written procedures for cleaning, disinfecting and sanitizing all equipment and work areas shall be developed and followed.

D. Written reports of inspections by state and local health authorities shall be kept on file in the facility with notations made of actions taken by the facility to comply with recommendations.

E. Drugs shall not be stored in the dietary department or any refrigerator or storage area utilized by the dietary department. (See Sections 604.4.B. and C.)

F. All walk-in refrigerators and freezers must be equipped with opening devices which will permit opening of the door from the inside at all times.

SECTION 809. MEAL SERVICE:

A minimum of three nutritionally adequate meals in each 24-hour period shall be provided for each patient unless otherwise directed by the patient's physician. Not more than 15 hours shall elapse between the servings of the evening meal and breakfast.

SECTION 810. REFRIGERATION, ICE AND DRINKING WATER:

At least one functional refrigerator shall be provided on each patient floor. Ice that meets the approval of the Department shall be available and precautions shall be taken to prevent contamination. Ice delivered to patient areas in bulk shall be in nonporous, easily cleanable covered containers. The ice scoop shall be stored in a sanitary manner with the handle at

no time coming in contact with the ice. Clean, sanitary drinking water shall be available and accessible in adequate amounts at all times.

CHAPTER 9 - MAINTENANCE

SECTION 901. MAINTENANCE:

An institutional structure, its component parts, facilities, and all equipment, such as sterilizers, anesthesia machines, elevators, furnaces, call systems, emergency lights, etc., shall be kept in good repair and operating condition.

CHAPTER 10 - LAUNDRY AND LINEN

SECTION 1001. LAUNDRY:

The hospital will assure that the laundry providing services to the hospital exercises every precaution to render all linen safe for reuse.

SECTION 1002. OPERATED BY HOSPITAL:

Hospitals operating laundries within the buildings accommodating patients shall provide proper insulation to prevent transmission of noises to patient areas. The laundry shall be well ventilated and the general air movement shall be from the cleanest areas to the most contaminated areas.

SECTION 1003. STORAGE:

A clean linen storage room and a soiled linen storage room shall be provided. These storage rooms shall be used solely for their intended purposes. The soiled linen storage room shall be provided with mechanical ventilation to the outside.

SECTION 1004. CLEAN LINEN:

1004.1 A supply of clean, sanitary linen shall be available at all times.

1004.2 Proper storage facilities shall be provided for keeping clean linen in sanitary condition prior to use.

1004.3 Clean linen shall be transported in closed conveyances used only for transporting clean linen.

SECTION 1005. SOILED LINEN:

1005.1 Soiled linen shall be kept in closed or covered containers while being collected, transported or stored and shall be stored separately from clean linen and patient areas. These containers shall be cleaned and disinfected frequently.

1005.2 All linen from patients with infectious or communicable diseases shall be placed in durable bags identified "contaminated" and transported in these closed bags to the soiled linen holding area or laundry.

1005.3 Soiled linen shall be neither sorted nor rinsed in patient rooms.

1005.4 Laundry operations shall not be carried out in patient rooms or where food is prepared, served or stored.

1005.5 Soiled linen room floors shall be cleaned daily. The entire room, including

ceilings and walls, shall be cleaned and disinfected weekly or as often as necessary to control odors and bacteria.

1005.6 If linen chutes are used, the linen shall be enclosed in bags before placing in the chute. Chutes shall be cleaned regularly.

1005.7 Personnel shall wash their hands thoroughly after handling soiled linen.

CHAPTER 11 - HOUSEKEEPING AND REFUSE DISPOSAL

SECTION 1101. HOUSEKEEPING:

1101.1 General: A facility shall be kept neat and clean. Accumulated waste material must be moved daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, windows and premises. There must be a rodent and insect control program for the facility. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times. Dry dusting and dry sweeping are prohibited.

1101.2 Disinfection and Room Cleaning: Upon discharge or transfer of a patient, all bedside equipment shall be cleansed and disinfected. Bed linen shall be removed and mattresses turned; if damaged, replaced. Beds shall be made with fresh linens to maintain them in a clean and sanitary condition for each patient.

1101.3 Employee Locker Rooms: Employee locker rooms shall be kept in a neat, clean and sanitary condition.

1101.4 Janitor Closets: Janitor closets, floors, walls, sinks, mops, mop buckets, and all equipment shall be cleaned daily or more often as needed. A supervisory hospital employee shall make frequent inspections to assure compliance.

SECTION 1102. REFUSE DISPOSAL:

1102.1 Storage and Disposal: All garbage and refuse shall be deposited in water-tight containers. These containers shall be covered and stored to prevent the entrance of flies and the creation of a nuisance. Rubbish and garbage shall be disposed of periodically and in accordance with local requirements.

1102.2 Refuse Containers: Garbage and trash containers shall be thoroughly cleansed.

1102.3 Contaminated Dressings and Pathological Waste: All contaminated dressings, pathological, and/or similar waste shall be properly disposed of by incineration or other approved means.

1102.4 Radioactive Waste: All radioactive waste shall be disposed of by a method acceptable to the Department's Bureau of Radiological Health.

1102.5 Outside Areas: All outside areas, grounds and/or adjacent buildings on the premises shall be kept neat and clean.

CHAPTER 12 - FIRE PREVENTION AND PROTECTION

SECTION 1201. ARRANGEMENTS FOR FIRE DEPARTMENT PROTECTION:

Where a facility is located outside of a service area or a range of a public fire department, arrangements shall be made to have the nearest fire department respond in the case of fire. A copy of the agreement will be kept on file in the facility and a copy will be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

SECTION 1202. TESTS AND INSPECTIONS:

1202.1 Fire Protection:

A. The licensee is responsible for assuring that all standpipes, hoses, sprinkler systems, and other fire fighting equipment are inspected and tested at least once each year and more often if necessary to maintain them in serviceable condition. Fire extinguishers shall be kept in condition for instant use and the date of the last inspection shall be included on each fire extinguisher. Records of other inspections shall be kept on file.

B. Fire alarm systems shall be tested at least monthly and records kept on file.

1202.2 Electrical Inspections: The licensee is responsible for assuring that all electrical installations and equipment are maintained in a safe, operable condition.

1202.3 Heating, Ventilating and Air Conditioning Systems and Equipment: The licensee is responsible for assuring that all heating, ventilating and air conditioning equipment is maintained in a safe, operable condition.

SECTION 1203. SPECIAL HAZARDS:

1203.1 General:

A. Electrical apparatus located below a height of five feet from the floor in areas where combustible gases are used or stored shall be of explosive proof type or intrinsically safe as approved by the Underwriters Laboratory for use in hazardous locations.

B. High Frequency Electrical Apparatus: At no time shall the use of open lights of any description, unless approved by the Underwriters Laboratory, high frequency electrical apparatus, live cauteries or any other source of ignition in the vicinity of combustible anesthetics be permitted.

C. When purchasing new mattresses and pillows, only those providing the maximum resistance to fire, smoke development and toxicity must be purchased. These items present an unusual and severe fire hazard to the facility and extreme caution must be exercised in their selection.

1203.2. Smoking: Smoking shall be prohibited in surgical and delivery suites or similar hazardous areas (except in locker rooms), or within 10 feet of doorway of any room or within the room in which combustible anesthetics or oxygen are being used or stored.

1203.3 Storage Areas: All storage space shall be kept clean, orderly and free of trash, papers, old cloths and empty boxes. Any area exceeding 100 square feet shall not be used for storage unless it meets the requirements of Section 2107 of these Standards. Combustible materials such as mattresses, bedding and furniture shall be stored only in areas that meet the requirements of Section 2107. In areas provided with a sprinkler system, a minimum vertical distance of 18 inches shall be maintained between the top of stored items and the sprinkler heads.

1203.4 Hoods, Vents, Ducts: Hoods, vents, ducts and removable filters installed over cook stoves and ranges shall remain clean and free of grease accumulations. An exhaust fan of the proper size shall be installed over the unit and vented to the outside. An automatic fire extinguishing system shall be installed as outlined in NFPA No. 96.

SECTION 1204. CORRIDOR OBSTRUCTIONS:

Halls, corridors and all other means of egress from the building shall be maintained free of obstructions.

SECTION 1205. EXIT SIGN ILLUMINATION:

Exit signs shall be internally illuminated at all times.

SECTION 1206. HALLWAY AND STAIRWAY ILLUMINATION:

Hallways, stairs and other means of egress shall be lighted at all times with a minimum of one foot-candle at floor level.

SECTION 1207. PLANS AND TRAINING FOR FIRES AND OTHER INTERNAL EMERGENCIES:

A. Plans: Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire and other emergencies. All employees shall be made familiar with these plans and instructed as to required actions.

B. Fire protection training: Each employee shall receive instructions covering:

1. The fire plan;
2. The fire evacuation plan, routes and procedures;

3. How to report a fire;
4. How to use the fire alarm system;
5. The location and use of fire-fighting equipment;
6. Methods of fire containment;
7. Specific responsibilities of all personnel; and
8. Specific responsibilities of the individual.

C. Fire drills: A fire drill shall be conducted for each shift at least once every three months, i.e., each employee should participate in a fire drill at least once in any three-month period. Records of drills shall be maintained to report the date, time, shift and a description and evaluation of the drill.

D. Drills shall be designed and conducted to:

1. Assure that all personnel are capable of performing assigned tasks or duties;
2. Assure that all personnel know the location, use and how to operate fire-fighting equipment;
3. Assure that all personnel are thoroughly familiar with the fire plan; and
4. Evaluate the effectiveness of plans and personnel.

CHAPTER 13 - GENERAL

SECTION 1301. GENERAL:

Conditions which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.

(CHAPTERS 14-19 RESERVED)

PART II - PHYSICAL PLANT

CHAPTER 20 - DESIGN AND CONSTRUCTION

SECTION 2001. GENERAL:

Every facility shall be planned, designed and equipped to provide adequate facilities for the care, safety, and treatment of each patient.

SECTION 2002. LOCAL AND STATE CODES AND STANDARDS:

Facilities shall substantially comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. No facility will be licensed unless the Department has assurance that responsible local officials sanction the licensing of the facility. Buildings designed in accordance with the following codes will be acceptable to the Department provided, however, that the minimum requirements as set forth in these standards are met. The Department uses as its basic codes: **

- (1) Standard Building Code
- (2) Standard Plumbing Code
- (3) Standard Mechanical Code
- (4) Standard Gas Code
- (5) National Electrical Code (NFPA No. 70)

**Check with the Department to verify current editions.

SECTION 2003. SUBMISSION OF PLANS AND SPECIFICATIONS:

2003.1 New Buildings, Additions or Major Alterations to Existing Buildings:

When construction is contemplated either for new buildings, additions or major alterations to existing buildings, buildings being licensed for the first time, or buildings changing license type, plans and specifications shall be submitted in duplicate to the Department for review. Such plans and specifications shall be prepared by an architect and/or engineer registered in the State of S.C. and shall bear their seals and signatures. These submissions should be made in at least three stages: schematic, design development, and final. All plans shall be drawn to scale with the title and date shown thereon. Any construction changes from the approved documents shall have approval from the Department. Construction work should not be started until approval of the "final" construction documents or written permission to begin construction has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for supervision and inspections.

A. Schematic Plan Submission:

1. Site plan:

- a. Size and shape (meet and bounds) of the site;
- b. Footprint of the proposed building and/or addition on the site;
- c. Vehicular and pedestrian access to and on the site;
- d. Existing utilities for or to the site;
- e. Spot elevations and general information of the lay of the land (rivers, creeks, ridges, swamps, etc.);
- f. Existing structures (buildings, foundations, retaining walls above and underground storage tanks, etc.);

2. Floor Plan(s):

- a. Blocked spaces (areas) showing approximate size and relationship to other spaces.

3. Building Section:

- a. Type of construction;
- b. Type of structural system.

B. Design Development Plans Submission:

1. Cover Sheet:

- a. Title and location of project;
- b. Index of drawings;
- c. Code analysis listing applicable codes;
- d. Occupancy classification;
- e. Type of construction;
- f. Legend and notes and symbols for pertinent information.

2. Site plan shall include all the requirements of the schematic as well as:
 - a. Vehicular movement, parking areas (total number of spaces), sidewalks, etc.;
 - b. Existing and proposed contours;
 - c. All utilities to the facility (including water supply available for fire protection).
3. Building Section shall include all the requirements of the schematic as well as:
 - a. Complete building section showing the type of construction, floor to floor height;
 - b. Type of structural system;
 - c. Interior wall sections.
4. Floor Plans:
 - a. Complete plans drawn to scale with basic and overall dimensions of rooms and room designations;
 - b. Life safety plan showing proper delineation of rated walls (fire walls, smoke partitions, exits and exit calculations, etc.);
 - c. Door swings and sizes;
 - d. Fixed equipment locations;
 - e. Details.
5. Plumbing:
 - a. Fixture locations, risers and pipe chases.
6. Mechanical:
 - a. Type and location of equipment;
 - b. Single line drawing showing supplies, returns, and exhaust.
7. Electrical:
 - a. Lighting;
 - b. Power;

- c. Communication (nurse call, fire alarm);
- d. Electrical riser diagrams.

C. Final Drawings Submission: The final drawings shall include a complete set of contract documents including working drawings and contract specifications to include:

- 1. Site preparation;
- 2. Demolition (if required);
- 3. Architectural;
- 4. Structural;
- 5. Plumbing;
- 6. Mechanical;
- 7. Electrical;
- 8. Fire Protection (sprinkler);
- 9. Separate kitchen plan.

D. If construction is delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

E. One complete set of “as-built” drawings shall be filed with the Department.

2003.2 Alterations in Licensed Facilities: When alterations are contemplated that may affect life safety, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure the proposed alterations comply with current safety and building standards. All alterations or renovations of a part of an existing licensed building, other than cosmetic (i.e., painting, wallpapering or carpeting) shall be made to conform with the requirements of the current editions of the building codes for construction of new facilities. Only renovations and new construction shall be required to comply with current editions of codes. Facilities, or sections of facilities, shall be surveyed under the editions of the codes which were applicable at the time of initial licensing of that portion of the facility. Cosmetic changes utilizing paint, wallcovering, floor covering, etc., that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications furnished to the Department. Any existing building which is being licensed for the first time will be considered “new” construction and must meet current codes.

SECTION 2004. LOCATION:

2004.1 Environment: Facilities shall be located in an environment that is conducive to the type of care and services provided.

2004.2 Transportation: Facilities must be served by roads which are passable at all times and are adequate for the volume of expected traffic. Facilities shall maintain adequate access to and around the building(s) for fire fighting equipment.

2004.3 Parking: The facility shall have parking space to satisfy the minimum needs of patients, employees, staff and visitors. Provisions must be made for handicap parking.

2004.4 Communications: There must be a telephone on each floor occupied by patients and additional telephones or extensions as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

CHAPTER 21 - GENERAL CONSTRUCTION REQUIREMENTS

SECTION 2101. HEIGHT AND AREA LIMITATIONS:

Construction shall not exceed the allowable heights and areas for Group I, Institutional Occupancy, as provided by the Standard Building Code.

EXCEPTION: The above requirement does not apply to existing facilities; however, such facilities shall not be altered, remodeled or enlarged so as to exceed the height and area limitations as set forth in the Standard Building Code.

SECTION 2102. FIRE-RESISTIVE RATING:

The fire-resistive ratings for the various structural components shall comply with the Standard Building Code. Fire-resistive ratings of various materials and assemblies not specifically listed in the Standard Building Code can be found in the publication entitled, "Underwriters Laboratories - Building Material List."

EXCEPTION: The fire-resistive rating for facilities licensed prior to May 1968 shall be at least one hour; however, this requirement shall not apply if one or more of the following conditions are met:

1. The entire building is equipped with an approved automatic sprinkler system;
2. Partitions and ceilings are constructed of or are covered with materials that will provide a fire-resistive rating of at least one hour, and an approved fire alarm system is provided.

SECTION 2103. VERTICAL OPENINGS:

A. Walls enclosing stairways, elevator shafts, chutes, discharge rooms for chutes and other vertical shafts shall be of at least two-hour fire-resistive construction. Laundry, trash and incinerator chutes shall be equipped with an automatic sprinkler system.

B. Service openings to chutes, dumbwaiters, conveyors and other material handling systems shall not be located in corridors or passageways but shall be located in a room enclosed by construction having at least a one-hour fire-resistive rating. Doors to such rooms shall not be less than "C" labeled, 3/4-hour fire-rated doors. Service entrance doors to chutes and to vertical shafts containing dumbwaiters, conveyors and material handling systems shall be not less than "B" labeled, 1 1/2-hour fire-rated doors, and shall be self-closing.

EXCEPTIONS: Items A and B above do not apply to facilities licensed prior to May 1968.

SECTION 2104. WALL AND PARTITION OPENINGS:

All wall and partition openings shall be protected in accordance with the provisions of the Standard Building Code.

SECTION 2105. CEILING OPENINGS:

Openings into attic areas or other concealed spaces shall be protected by material consistent with the fire rating of the assembly they are penetrating.

SECTION 2106. FIRE WALLS:

A building is defined by the outside walls and any interior four-hour fire walls and must not exceed the height and area limitations set forth in the Standard Building Code for the type of construction. An addition shall be separated from an existing building by a two-hour fire-rated wall unless the addition is of equal fire-resistive rating (for example: sprinklered and nonsprinklered areas). When an addition is to be constructed of a different type of construction from the existing building, the type of construction and resulting maximum area and height limitations allowed by the building code will be determined by the lesser of the types of construction for the building. If the addition is separated by a four-hour fire wall, the addition is considered as another building and the type of construction of the addition determines the maximum area and height limitations.

SECTION 2107. STORAGE AREAS:

A. Areas used for storage of combustible materials and storage areas of 100 square feet or greater shall be equipped with an approved automatic sprinkler system.

B. Walls, ceilings and floor assemblies enclosing storage areas of 100 square feet or greater shall be of not less than one-hour fire-resistive construction with "C" labeled, 3/4-hour fire-rated doors and frames.

EXCEPTION: Item B above does not apply to facilities licensed prior to May 1968.

SECTION 2108. ALTERATIONS AND REPAIRS:

If, within any 12-month period, alterations or repairs costing in excess of 50 percent of the then physical value (market value) of the building are made to an existing facility, such building shall be made to conform with the requirements of the current edition of the Standard Building code for construction of new facilities and to the requirements of these Standards.

SECTION 2109. FLOOR CONSTRUCTION:

Wood joists, wood subfloors and wood finish floors are not permitted for floor construction.

EXCEPTION: The above does not apply to facilities licensed prior to May 1968.

SECTION 2110. CARPETING:

Interior floor finishes including carpeting, shall be in accordance with the Standard Building Code for the type of occupancy. Carpet is permitted as a floor finish only if certified by an independent testing laboratory as having a flame-spread rating of not more than 75 when tested under ASTM E-84 or not less than .45 watts/sq. cm. when tested under either ASTM-E-648 or NFPA No. 253. Unless the padding was tested as a part of the tested assembly, only a hair or jute pad will be acceptable.

CHAPTER 22 - HAZARDOUS ELEMENTS OF CONSTRUCTION

SECTION 2201. FURNACES AND BOILERS:

A. Every central heating boiler and furnace shall be enclosed and separated from the rest of the building by walls, partitions, floors and ceiling assemblies having at least a two-hour fire-resistive rating with "B" labeled, 1 1/2-hour fire-rated door and frame.

B. Installation of central heating boilers and furnaces shall be in accordance with applicable NFPA standards.

C. Maintenance of heating boilers and furnaces shall be provided to insure efficient and safe operation.

EXCEPTION: Item A above does not apply to facilities licensed prior to May 1968.

SECTION 2202. DAMPERS:

Smoke and fire dampers shall be installed on all heating, cooling and ventilating systems as required by NFPA No. 90A, "Conditioning and Ventilating Systems."

EXCEPTION: The above does not apply to facilities constructed prior to April 23, 1979.

SECTION 2203. INCINERATORS:

Incinerators shall conform with the requirements of the Department. When located within the licensed facility, they shall be separated by construction having at least two-hour fire-resistive rating with "B" labeled, 1-1/2 hour fire-rated door(s) and frame(s).

SECTION 2204. GASES:

Gases (flammable and nonflammable) shall be handled and stored in accordance with the provisions of applicable NFPA No. 99 "Health Care Facilities".

SECTION 2205. FLAMMABLE LIQUIDS:

The storage of flammable liquids shall be in accordance with NFPA No. 30, "Flammable and Combustible Liquids Code" and NFPA No. 99 "Health Care Facilities."

CHAPTER 23 - SCREENS

SECTION 2301. SCREENS:

Windows, doors and openings intended for ventilation shall be provided with insect screens unless the facility is completely air conditioned and mechanically ventilated.

CHAPTER 24 - FIRE PROTECTION

SECTION 2401. FIRE FIGHTING EQUIPMENT:

Facilities licensed under these standards shall be provided throughout with a complete automatic sprinkler system in accordance with NFPA No. 13, "Standard for the Installation of Sprinkler Systems". Fire fighting equipment such as fire extinguishers and standpipes shall be provided as required by the Standard Building Code. Extinguishers shall be located so that a person will not have to travel more than 75 feet from any point within the facility to reach an extinguisher, and within 25 feet of exits in corridors. Extinguishers shall be sized, located, installed and maintained in accordance with NFPA No. 10, except that portable fire extinguishers intended for use in patient areas shall be of the 2-A, 2-1/2 gallon stored-pressure water type. A 4-A:20-BC fire extinguisher shall be installed in the following hazardous areas: laundry, furnace room and any other area having an unusual fire hazard. At least one 2-A:10-BC type fire extinguisher shall be located at each nurses' station. The kitchen shall be equipped with a minimum 20-BC extinguisher.

SECTION 2402. ALARMS:

A. A manual fire alarm system in accordance with provisions of NFPA No. 72A shall be provided. The system shall be arranged to transmit an alarm automatically to the fire department by an approved method.

B. The alarm system shall notify by audible and visual alarm all areas and floors of the building.

C. The alarm system shall shut down central recirculating ventilation fans that serve the area(s) of alarm origination and shut the associated smoke dampers.

D. There must be a fire alarm pull station in or near each nurses station.

E. All fire, smoke, heat, sprinkler flow, or manual fire alarming devices or systems must be connected to the main fire alarm system and trigger the system when they are activated.

SECTION 2403. DETECTION SYSTEM:

A. An approved automatic smoke detection system shall be installed in all corridors. Such systems shall be installed in accordance with the applicable NFPA standards, but in no case shall smoke detectors be spaced farther apart than 30 feet on centers or more than 15 feet from any wall.

B. All automatic detectors shall be electrically interconnected to the fire alarm system as well as to all hold-open devices on smoke doors and fire doors within a fire zone.

EXCEPTION: Where each patient sleeping room is protected by such an approved detection system and a local detection system is provided at the smoke partition, such

corridor system will not be required on the patient sleeping room floors.

C. Where smoke detectors are required in all sleeping rooms, the detectors will be powered by the fire alarm system, connected to the fire alarm system, and have an indicator light in the hall above the room door indicating when the detector is in alarm.

CHAPTER 25 - EXITS

SECTION 2501. NUMBER AND LOCATIONS:

A. There shall be more than one exit leading to the outside of the building from each floor.

B. Exits shall be placed so that the entrance door of every private room and semiprivate room, and every point in open wards, day rooms, dormitories, dining rooms, etc., shall be not more than 100 feet along the line of travel from the nearest exit. In buildings equipped with automatic sprinklers this distance shall be not more than 150 feet. Exits shall be remote from each other and shall be arranged so that there are no corridor pockets or dead ends of 20 feet or more in which occupants may be trapped.

EXCEPTION: Existing dead ends up to 30 feet are acceptable in facilities licensed prior to May 1968.

C. Each patient's room shall communicate directly with an approved exit corridor without passage through another occupied space or shall have an approved exit directly to the outside at grade level in an area of safety.

SECTION 2502. CORRIDORS:

2502.1 Corridor Width: Corridors and passageways from patient occupied rooms leading to egress stairways and/or to the outside from the first story and to areas of refuge shall be a minimum of 96 inches in width.

EXCEPTION: In facilities licensed prior to May 1968, corridors having a width less than 96 inches are acceptable.

2502.2 Corridor Height: Corridors and passageways considered as approved means of egress shall be at least 84 inches in height.

EXCEPTION: The above section does not apply to facilities licensed prior to May 1968.

SECTION 2503. DOORS:

2503.1 Door Width: Exits, doors to patient rooms, and rooms that may be used by nonambulatory patients shall be at least 44 inches in width.

EXCEPTION: The above does not apply to facilities licensed prior to May 1968.

2503.2 Door Height: Doorways from patient occupied rooms and in egress passages to the outside of the building shall be at least 78 inches in height.

2503.3 Door Swing: The exit doors required from each floor shall swing in the direction

of egress travel. Doors, except those to spaces such as small closets which are not subject to occupancy, shall not swing into corridors in a manner that might obstruct traffic flow or reduce the required corridor width.

2503.4 Door Locks: Patient room doors shall not be lockable except in places of restraint or detention.

SECTION 2504. STAIRS:

Exit stairs shall conform to the requirements of the Standard Building Code. The floor on both sides of all required exit doors shall be at the same elevation for a distance at least equal to the width of the doors. The stair width shall be in accordance with the Standard Building Code.

EXCEPTION: The above does not apply to facilities licensed prior to May 1968.

SECTION 2505. RAMPS:

Exterior ramps with a slope of not more than one in twelve shall be installed from the first floor to the grade to serve all portions of the building where patients are or may be placed. Exterior ramps shall be not less than four feet in width in all areas occupied by patients or serving as part of the means of egress from patient areas. Interior ramps shall be the full width of the corridor. All ramps shall have level platforms at least four feet long at 30-foot intervals for purposes of rest and safety and shall have level platforms wherever they turn. All ramps shall be provided with approved handrails. All handrail ends adjacent to a wall must return to the wall. Surface of ramps shall be of nonskid materials.

EXCEPTION: The above does not apply to facilities constructed prior to April 23, 1979.

SECTION 2506. SMOKE BARRIERS:

Smoke partitions having a fire-resistive rating of at least one hour shall be provided to limit on any story the maximum area of each smoke compartment to no more than 22,500 square feet, either length or width shall not exceed 150 feet, and to divide every story into at least two compartments. At least 30 net square feet per occupant shall be provided on each side of the smoke partition. Smoke partitions shall be continuous from the floor slab to the underside of the floor or roof deck above, through any concealed spaces such as those above ceilings and through interstitial structural and mechanical spaces.

A. Openings in all smoke partitions shall be protected with a tight fitting smoke door having a fire-resistive rating of at least 20 minutes and shall be so labeled. Doors in smoke partitions shall have one face of the door opening to a public way or path of egress.

B. Doors in smoke partitions shall be self-closing and so maintained or shall be provided with approved door holding devices of the fail-safe type which will release the doors causing them to close when any of the following is activated.

1. Automatic sprinkler system;
2. Manual fire alarm system;
3. Smoke detection system.

C. Smoke partitions shall have openings in the corridors only. Corridor doors shall be a pair of swinging doors, each door to swing in a direction opposite from the other. The minimum width of each door shall be 44 inches. Doors in corridor openings shall have vision panels of 1/4 inch thick, wire-reinforced glass in approved frames not exceeding 1,296 square inches per door. Positive latching hardware is not required except in partitions rated at two hours or more and center mullions are prohibited. Opposite swing smoke partition doors shall have approved astragal. When it is necessary to use a shutter in a smoke partition, it must be motor operated and self resetting or have an internal brake and counter-balance such that the shutter will close slowly so as not to injure a person caught beneath it. When the shutter encounters an obstruction, it shall stop, but continue to close when the obstruction is removed.

EXCEPTION: This section does not apply to facilities constructed prior to April 23, 1979.

CHAPTER 26 - ENGINEERING

SECTION 2601. WATER SUPPLY/HYGIENE:

2601.1 Design and Construction: Before the construction, expansion, or modification of a water distribution system, application shall be made to the Department for a Permit for Construction. The application shall include such engineering, chemical, physical, or bacteriological data as may be required by the Department and shall be accompanied by engineering plans, drawings and specifications prepared by an engineer registered in S.C. and shall carry his official signature and seal. In general, the design and construction of such systems shall be in accord with modern engineering practices for such installations. The Department shall establish such rules, regulations, procedures or standards as may be necessary to protect the health of the public and to insure proper operation and functioning of the system.

2601.2 Disinfection of Water Lines: After construction, expansion, or modification, a water distribution system shall be disinfected in accordance with the requirements of the Department. Samples shall be taken from the water system and forwarded to an approved laboratory for bacteriological analysis in accordance with Department regulations. The water shall not be used as a potable supply until certified as satisfactory.

2601.3 Temperature Control: Plumbing fixtures which require hot water and which are accessible to patients shall be supplied with water which is thermostatically controlled to a temperature of at least 100 degrees F. (37.8 degrees C.) and not exceeding 125 degrees F. (51.7 degrees C.) at the fixture. The water heater or combination of heaters shall be sized to provide at least six gallons per hour per bed at the above ranges. Hot water supplied to the pot washing sink in the kitchen shall be supplied at 140 degrees F. The final rinse temperature of the dishwasher shall be 180 degrees F.

2601.4 Stop Valves: Each plumbing fixture and each piece of equipment shall have stop valves to permit repairs without disrupting service to other fixtures. Each group of fixtures on a floor, each branch main, and each supply line shall be valved.

EXCEPTION: This does not apply to facilities licensed prior to May 1968.

2601.5 Cross-connections: Cross-connections in plumbing between safe and potentially unsafe water supplies are prohibited. This refers particularly to toilets, instrument sterilizers, autoclaves, laundry fixtures and fixtures of similar nature. Water shall be delivered at least two delivery pipe diameters above the rim or points of overflow to each fixture, equipment or service unless protected against back siphonage by approved vacuum breakers or other approved back-flow preventers. A faucet or fixture to which a hose may be attached shall have an approved vacuum breaker or other approved back-flow preventer.

SECTION 2602. WASTEWATER:

2602.1 Design and Construction: Plans, specifications, reports and studies, for the construction, expansion or alteration of a wastewater system, shall be prepared by an engineer registered in S.C. and shall carry his official signature and seal. The design and construction of wastewater systems shall be in accordance with modern engineering practice and the rules and regulations of the Department.

2602.2 Fixtures:

A. Toilets: Toilets shall be provided in number ample for use according to number of patients. The minimum requirement is one toilet for every four patients or fraction thereof. Grab bars of an approved type shall be provided on at least one side of every toilet. Toilet facilities and locker rooms shall be provided for employees.

EXCEPTION: The number of toilets specified above does not apply to existing facilities constructed prior to April 23, 1979.

B. Lavatories: Every patient room shall have a lavatory unless there is an adjoining toilet with a lavatory. Every patient room lavatory, as well as all other lavatories used by doctors, nurses, or food handlers, shall be trimmed with valves which can be operated without the use of hands.

EXCEPTION: Section B does not apply to facilities licensed prior to May 1968.

C. Baths: The minimum requirement is a bathtub or shower with approved grab bars for each 12 patients or fraction thereof.

EXCEPTION: The number of bathtubs or showers specified above does not apply to facilities constructed prior to April 23, 1979.

D. Sinks and Handwashing Fixtures: A sink shall be provided at each nursing station and in each utility room. Separate handwashing fixtures shall be provided in the main kitchen and shall be so located that the person in charge may supervise handwashing by food service personnel. Handwashing fixtures shall be provided in other service rooms and adjacent to or in all toilets. Handwashing fixtures shall be equipped with valves which can be operated without the use of hands. Paper towel and soap dispensers shall be provided at each handwashing sink.

EXCEPTION: Section D does not apply to facilities licensed prior to May 1968.

SECTION 2603. ELECTRICAL REQUIREMENTS:

2603.1 Installation:

A. Materials, including equipment, conductors, controls and signaling devices, shall be installed to provide a complete electrical system with the necessary characteristics and capacity to supply the electrical equipment indicated in the specifications or shown on the

plans. All materials shall be listed as complying with available standards of Underwriters Laboratories, Inc., or other similarly established standards.

B. Electrical installations and systems shall be in accordance with the National Electrical Code. The fire alarm system shall be tested initially by a factory-trained manufacturer's representative. At the completion of construction and before occupancy, the architect or engineer shall certify that all electrical systems have been installed per specifications and have been thoroughly tested.

2603.2 Switchboard and Power Panels: Circuit breakers or fusible switches that provide disconnecting means and overcurrent protection for conductors connected to switchboards and panelboards shall be enclosed or guarded to provide a dead-front type of assembly. The main switchboard shall be located in a separate enclosure accessible only to authorized persons. The switchboard shall be convenient for use, readily accessible for maintenance, clear of traffic lanes, and in a dry, ventilated space free of corrosive fumes or gases. Overload protective devices shall be suitable for operating properly in ambient temperature conditions. Electrical circuits should be arranged and provided with switches in such a manner as to permit necessary preventive maintenance and testing of switches, connectors, circuit breakers and other such devices without interrupting power to essential lifesaving equipment.

EXCEPTION: The above does not apply to facilities which were constructed prior to April 23, 1979.

2603.3 Panelboards: Panelboards serving lighting and appliance circuits shall be located on the same floor as the circuits they serve. This requirement does not apply to life safety system circuits. The panelboard directory shall be labeled to conform to the actual room numbers or designations.

2603.4 Lighting:

A. Spaces occupied by people, machinery, equipment within buildings, approaches to buildings and parking lots shall be lighted.

B. Patient rooms shall have general lighting and night lighting. A reading light shall be provided for each patient. At least one light fixture for night lighting shall be switched at the entrance of each patient room. All switches for control of lighting in patient areas shall be of the quiet operating type. (This requirement does not apply to facilities constructed prior to April 23, 1979.)

2603.5 Receptacles (Convenience Outlets):

A. Patient Room: Each patient room shall have duplex grounding type receptacles located as follows: one on each side of the head of each bed; one for television, if used; and one on another wall.

EXCEPTION: In facilities constructed prior to April 23, 1979, the requirement for receptacles is at least one duplex convenience outlet in each private room or between each two beds in larger rooms for examining lights and similar equipment.

B. Corridors: Duplex receptacles for general use shall be installed approximately 50 feet apart in all corridors and within 25 feet of the ends of corridors.

EXCEPTION: Section B does not apply to facilities constructed prior to April 23, 1979.

2603.6 Ground Fault Protection: The electrical circuits to fixed or portable equipment in hydrotherapy units shall be provided with 5 milliampere ground fault interrupters. Ground fault interrupter receptacles shall be used on all outside receptacles and bathrooms per National Electrical Code. Ground fault interrupter receptacles or circuits shall be used at wet locations such as in or above a counter containing a sink when the receptacle is within three feet of the sink.

2603.7 Signal System: A signal system shall be provided for each patient. The system shall consist of a call button for each bed, bath, toilet and treatment/examination room; a light at or over each patient room door visible from the corridor; a control panel at the nurses' station showing room or bed number; and indicators in utility rooms, treatment/examination rooms, medication rooms, nurses' lounges and floor kitchens. Indicators and control panels shall employ both an audible and visual signal.

EXCEPTION: In existing facilities, either an audible or visual signal is acceptable.

2603.8 Exit Signs:

A. Required exits and ways of access thereto shall be identified by illuminated (electric) signs bearing the word "Exit" or "Fire Escape" in red letters at least six inches in height, on a white background. Changes in direction of exit travel shall be suitably marked by exit signs with directional arrows.

EXCEPTION: In facilities licensed prior to May 1968, the existing four-inch letters are acceptable.

B. Circuits: Illuminated signs shall be on a life safety circuit or circuits and shall be serviced and controlled directly from the life safety panel. Exit signs shall be connected to the emergency power system.

2603.9 Emergency Electric Service:

A. To provide electricity during an interruption of the normal electric supply, adequate emergency generator service shall be provided.

B. Emergency electric services shall be provided to the distribution system as follows:

1. Illumination for means of egress and nurses' stations;
2. Illumination for exit signs and exit directional signs;
3. Duplex receptacles in patient area corridors or in patient rooms;
4. Nurses' signal system;
5. Equipment necessary for maintaining telephone service;
6. Elevator service that will reach every patient floor when patient rooms are located on other than the ground floor. Throwover facilities shall be provided to allow temporary operation of any elevator for release of persons who may be trapped between floors.
7. Fire pump;
8. Equipment for heating patient rooms and maintaining a minimum temperature of 71 degrees F.;
9. General illumination and selected receptacles in the vicinity of the generator set;
10. Alarm systems, including fire alarms, water-flow alarm devices of sprinkler systems, fire and smoke detecting systems, and alarms required for nonflammable medical gas systems;
11. Illumination and selected receptacles in infant nurseries; medicine dispensing areas; cardiac catheterization laboratories, angiographic laboratories, labor, operating, delivery and recovery rooms; dialysis units; intensive care areas; emergency treatment rooms and blood bank locations;
12. Illumination in public restrooms.

C. Details: The emergency power shall be in operation within 10 seconds after interruption of the normal electric power supply. Receptacles connected to emergency power shall be distinctively marked. On-site fuel storage shall have such capacity to sustain emergency generator operation for 24 hours. Emergency generators shall be operated weekly for at least 30 minutes, including a monthly test under "load" conditions. Logs shall be maintained of emergency generator tests.

SECTION 2604. MECHANICAL SYSTEMS:

Prior to licensure of the facility, all mechanical systems shall be tested, balanced and operated to demonstrate that the installation and performance of these systems conform to the requirements of the plans and specifications.

2604.1 Thermal and Acoustical Insulation:

A. Insulation shall be provided for the following within the building:

1. Boilers, smoke breeching and stacks;
2. Steam supply and condensate return piping;
3. Hot water piping above 180 degrees F. (82.2 degrees C.) and all hot water heaters, generators and converters;
4. Hot water piping above 125 degrees F. (51.7 degrees C.) which is exposed and subject to contact by occupants;
5. Chilled water, refrigerant, other process piping and equipment operating with fluid temperatures below ambient dew point;
6. Water supply and drainage piping on which condensation may occur;
7. Air ducts and casings with outside surface temperatures below ambient dew point;
8. Other piping, ducts and equipment as necessary to maintain the efficiency of the system.

B. Insulation may be omitted from hot water and steam condensate piping not subject to contact by occupants when such insulation is unnecessary for preventing excessive system heat loss or excessive heat gain.

C. Insulation on cold surfaces shall include an exterior vapor barrier.

D. Insulation including finishes and adhesives on the exterior surfaces of ducts, pipes and equipment shall have a flame-spread rating of not more than 25 and a smoke developed rating of not more than 150 as determined by an independent testing laboratory in accordance with ASTM Standard E-84.

E. Linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters Laboratories Publication No. 181. These linings, including coatings and adhesives, and insulation on exterior surfaces of pipes and ducts in building spaces used as air supply plenums shall have a flame-spread rating of not more than 25 and a smoke developed rating of not more than 50 as determined by an independent testing laboratory in accordance with ASTM Standard E-84.

F. No HVAC supply or return grill will be placed within three feet of a smoke detector.

2604.2 Steam and Hot Water Systems:

A. Boilers shall have the capacity, based upon the net ratings published by Hydronics Institute, to supply the normal requirements of all systems and equipment. The number and arrangement of boilers shall be such that when one boiler breaks down or routine maintenance requires that one boiler be temporarily taken out of service, the capacity of the remaining boilers shall be at least 70 percent of the total required capacity.

B. Boiler feed pumps, heating circulating pumps, condensate return pumps and fuel oil pumps shall be connected and installed to provide normal and standby service.

C. Supply and return mains and risers of cooling, heating and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends.

2604.3 Heating and Ventilating Systems:

A. Temperatures and Humidities: Minimum design temperature of 75 degrees F. (23.9 degrees C.) at winter design conditions and 81 degrees F. maximum summer design conditions shall be provided for all occupied areas not listed below. The systems shall be designed to provide the following temperatures and humidities in the areas noted:

<u>Area Designation</u>	<u>Temperature</u>		<u>Relative Humidity</u>	
	<u>EF</u>	<u>EC</u>	<u>Minimum</u>	<u>Maximum</u>
Operating Room	70-76	21.1 - 24.4	50	60
Delivery Rooms	70-76	21.1 - 24.4	50	60
Recovery Rooms	75	23.9	50	60
Intensive Care Units	75-80	23.9 - 26.7	30	60
Nurseries	72-76	22.2 - 24.4	30	60
Special Care Nurseries	75-80	23.9 - 26.7	30	60

B. Ventilation System Details: Air supply and air exhaust systems shall be mechanically operated. Fans serving exhaust systems shall be located at the discharge end of the system. The ventilation rates shown in Table I shall be considered as minimum acceptable rates and shall not be construed as precluding the use of higher ventilation rates.

1. Outdoor air intakes shall be located as far away as practical but in no case closer than 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vent stacks or from areas which may collect vehicular exhaust and other noxious fumes. The bottom of outdoor air intakes serving central systems shall be located as high as practical but not less than six feet above ground level, or if installed above the roof, three feet above roof level.

2. The ventilation systems shall be designed and balanced to provide the pressure relationships as shown in Table I.

3. The bottoms of ventilation openings shall be not less than three inches above the floor of any room.

4. Corridors shall not be used to supply air to or exhaust air from any room except that air from corridors may be used to ventilate bathrooms, toilet rooms, janitor closets and small electrical or telephone closets opening directly on corridors.

5. Central ventilation or air conditioning systems shall be equipped with filters having efficiencies no less than those specified in Table II. Where two filter beds are required, filter bed No. 1 shall be located upstream of the air conditioning equipment and filter bed No. 2 shall be downstream of the supply fan, any recirculating water spray system and water reservoir type humidifier. Where only one filter bed is required, it shall be located upstream of the air conditioning equipment.

6. Filters' efficiencies shall be average atmospheric dust spot efficiencies tested in accordance with ASHRAE Standard 52-68. Filter frames shall be durable and carefully dimensioned and shall provide an air-tight fit with the enclosing duct work. Joints between filter segments and the enclosing duct work shall be gasketed or sealed to provide a positive seal against air leakage. A manometer shall be installed across each filter bed serving central air systems.

7. Air handling duct systems shall meet the requirements of NFPA No. 90A.

8. Fire and smoke dampers shall be constructed, located and installed in accordance with the requirements of NFPA No. 90A except that all systems, regardless of size, which serve more than one smoke or fire zone, shall be equipped with smoke detectors connected to the fire alarm system to shut down fans automatically upon the detection of smoke. Access for maintenance shall be provided at all dampers. Supply and exhaust ducts which pass through a required smoke barrier and through which smoke can be transferred to another area shall be provided with dampers at the barrier, controlled to close automatically to prevent flow of air or smoke in either direction when the fan, which moves the air through the duct, stops. Dampers shall be equipped with remote control reset devices.

9. Exhaust hoods in food preparation centers shall have an exhaust rate of not less than 50 cfm per square foot of face area. Face area is defined for this purpose as the open area from the exposed perimeter of the cooking surfaces. Hoods over cooking ranges shall be equipped with grease filters, fire extinguishing systems in accordance with NFPA No. 96A and heat actuated fan controls. Cleanout openings shall be provided every 20 feet in horizontal exhaust duct systems serving these hoods. The hood extinguishing system must shut off all power to heating and cooking equipment located under the hood when the hood extinguishing system is triggered.

10. Boiler rooms shall be provided with sufficient outdoor air to maintain combustion rates of equipment and to limit temperatures in working stations to 97E F (36.1E C.)

Effective Temperature (ET*) as defined as ASHRAE Handbook of Fundamentals.

TABLE I
PRESSURE RELATIONSHIPS AND VENTILATION RATES
SELECTED AREAS OF HOSPITAL AREAS²

AREA DESIGNATIONS	1	2	3	4	5
Operating Room	P	15	3	OPT	NO
Emergency Operating Room	P	15	3	OPT	NO
Delivery Room	P	12	5	OPT	NO
X-Ray Cd Cath. & Invas. Spec. Proc.	P	15	3	OPT	NO
Newborn Nursery	P	6	1	OPT	NO
Recovery Room	P	6	2	OPT	NO
Intensive Care	P	6	2	OPT	NO
Trauma Room	P	15	3	OPT	NO
Patient Room	E	2	2	OPT	OPT
Labor/Delivery (LDR)	E	2	2	OPT	OPT
Patient Corridor	E	2	4	OPT	OPT
Examination and Treatment	E	6	2	OPT	OPT
X-Ray, Fluoroscopy	N	6	2	YES	NO
X-Ray, Treatment	E	6	2	OPT	OPT
Medication Room	E	4	2	OPT	OPT
Pharmacy	E	4	2	OPT	OPT
Physical Therapy Hydrotherapy	N	6	2	OPT	OPT
Treatment	E	6	2	OPT	OPT
Occupational Therapy	N	6	2	OPT	OPT
Soiled Workroom	N	10	2	YES	NO
Soiled Holding Room	N	10	2	YES	NO
Autopsy Room	N	12	2	YES	NO
Workroom	N	10	2	YES	NO
Darkroom	N	10	2	YES	NO
Body Holding Room	N	10	2	YES	NO
Bedpan Room	N	10	2	YES	YES
Toilet Room	N	10	2	YES	YES
Bathroom	E	10	2	OPT	OPT
Clean Util. Workroom	P	4	2	OPT	OPT
Clean Util. Holding Room	P	4	2	OPT	OPT
Janitor Closets	N	10	2	YES	NO
Sterilizer Equipment	N	10	2	YES	NO
Linen/Trash Chute Room	N	10	2	YES	NO
ETO Sterilizer Room	N	10	2	YES	NO
Laboratory					

General	E	6	2	OPT	OPT
AREA DESIGNATIONS	1	2	3	4	5
Nuclear Medicine	N	6	2	YES	NO
Pathology	N	6	2	YES	NO
Cytology	N	6	2	YES	NO
Biochemistry	P	6	2	OPT	NO
Histology	N	6	2	YES	NO
Microbiology	N	6	2	YES	NO
Serology	P	6	2	OPT	NO
Glass Washing	N	10	2	YES	OPT
Sterilizer	N	10	2	YES	OPT
Media Transfer	P	4	2	OPT	NO
Food Preparation Center	E	10	2	YES	NO
Ware Washing	N	10	2	YES	NO
Dietary Day Storage	N	2	OPT	OPT	OPT
Trash Room	N	10	2	YES	NO
Laundry, General	E	10	2	YES	NO
Soiled Linen Sorting and Storage	N	10	OPT	YES	NO
Clean Linen Storage	P	2	2	OPT	OPT
Special Procedures Rooms					
Invasive	P	15	3	OPT	NO
Non-invasive	E	6	2	OPT	OPT
Isolation Room	SETABLE ¹	6	2	YES	NO
Anesthesia Gas Storage	E	3	OPT	YES	NO
Central Supply					
Soiled or Decontm. Rm.	N	6	2	YES	NO
Clean Workroom &					
Sterile Storage	P	4	2	OPT	OPT
Unsterile Supply Stg.	E	2	2	OPT	OPT

COLUMN 1 = AIR PRESSURE RELATIONSHIP TO ADJACENT AREAS ²

COLUMN 2 = MINIMUM TOTAL AIR CHANGES PER HOUR SUPPLIED TO ROOM

COLUMN 3 = MINIMUM AIR CHANGES OF OUTSIDE AIR PER HOUR SUPPLIED TO ROOM

COLUMN 4 = ALL AIR EXHAUSTED DIRECTLY TO OUTSIDE

COLUMN 5 = AIR RECIRCULATED WITHIN ROOM BY MEANS OF ROOM UNITS

OPT = OPTIONAL

N = NEGATIVE - Air moves into room from adjacent spaces

P = POSITIVE - Air moves out of room into adjacent spaces

E = EQUAL - Air is not forced to move into or out of room from adjacent spaces

¹ Pressure relationship can be adjustable according to conditions necessary for treatment.

² Specialized patient care areas including organ transplant units, burn units, specialty procedure rooms, etc., shall have additional ventilation provisions for quality control as may be appropriate.

TABLE II

Area Designation	Minimum Number of Filter Beds	Filter Efficiencies (%)	
		Filter Bed No. 1	Filter Bed No. 2
Sensitive Areas*	2	25	90
Patient Care, Treatment, Diagnostic, and Related Areas	2	25	90**
Food Preparation Areas and Laundries	1	80	--
Administrative, Bulk Storage, and Soiled Holding Areas	1	25	--

*Includes OR, OB, Nurseries, Recovery Rooms, Intensive Care Units.

**May be reduced to 80% for systems using all outdoor air.

2604.4 Other Piping Systems:

A. Domestic Hot Water Systems:

1. The hot water heating equipment shall have sufficient capacity to supply water at the temperature and amounts indicated below. Water temperatures to be taken at hot water point of use or inlet to processing equipment:

	<u>USE</u>		
	<u>Clinical</u>	<u>Dietary</u>	<u>Laundry</u>
Gallons (per hour per bed)	6-1/2	4	4-1/2
Temperature	100 degrees F. (37.80 C.)	180 degrees F. (82.2 C.)	180 degrees F. (82.2 C.)

2. Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times.

3. Storage tanks shall be fabricated of corrosion-resistant metal or lined with noncorrosive material.

B. Drainage Systems: Insofar as possible, drainage piping shall not be installed within the ceiling nor installed in an exposed location in food preparation centers, food serving facilities, food storage areas and other critical areas. Special precautions shall be taken to protect these areas from possible leakage or condensation from necessary overhead piping

systems.

C. Medical Gas Systems: Flammable and nonflammable medical gas system installations shall be in accordance with the requirements of NFPA No. 99.

D. Clinical Vacuum (Suction) Systems: If used, clinical vacuum system installations shall be in accordance with the requirements of Compressed Gas Association Pamphlet P-2.1.

EXCEPTION: Section 2604 does not apply to facilities constructed prior to April 23, 1979.

CHAPTER 27 - FACILITIES

SECTION 2701. PATIENT ROOMS:

2701.1 Interpretation: A patient's room shall be interpreted as an area enclosed by ceiling high walls. In using the Standard Building Code, each patient room is a separate tenancy. No rooms in basements shall be used for patients. Each patient's room shall be an outside room with an outside window.

2701.2 Floor Area:

A. The following allowance of floor space is a minimum: The floor area is defined as usable or net area and does not include wardrobes, closets, or the entry alcove to the room. Rooms for only one patient--100 square feet. Rooms for two or more patients--80 square feet per bed.

B. Beds must be placed at least three feet apart.

C. At least one private room shall be provided in each nursing unit for purposes of medical isolation, incompatibility, personality conflicts, etc.

D. No patient room shall contain more than four beds.

EXCEPTION: Items A and D do not apply to facilities licensed prior to May 1968. Item D does not apply to critical care areas.

2701.3 Windows: Glass in Windows and Mirrors: Where clear glass is used in windows, with any portion of the glass being less than 18 inches from the floor, the glass shall be of "safety" grade, or there shall be a guard or barrier over that portion of the window. This guard or barrier shall be of sufficient strength and design so that it will prevent someone from injuring themselves by accidentally stepping into or kicking the glass.

EXCEPTION: The window area specified above does not apply to facilities licensed prior to May 1968.

2701.4 Storage Space: Storage space shall be provided for clothing, toilet articles, and personal belongings of patients.

2701.5 Floor, Wall and Ceiling Material: The interior finish of walls and ceilings throughout shall be in accordance with the Standard Building Code requirements for "Interior Finishes - Institutional, Unrestrained Occupancy".

2701.6 Patient Room Location: No patient's room shall be located more than 120 feet from the nurses' station.

2701.7 Cubicle Curtains, Draperies and Wastebaskets:

A. Cubicle curtains with built-in curtain tracks shall be provided in all multiple bed rooms which will shield each patient completely. Curtains will be flameproof.

EXCEPTION: In psychiatric and in chemical and substance abuse treatment units, cubicle curtains and tracks are not required if they pose a threat to patient safety. However, other arrangements must be made to ensure privacy when needed or requested by a patient.

B. All window draperies and curtains shall be flameproof.

C. All wastebaskets shall be of noncombustible materials.

SECTION 2702. NURSES' STATION:

2702.1 A nurses' station shall be provided. The nurses' station shall contain at least a telephone, a bulletin board, a refrigerator, and space for keeping patients' charts as well as for doctors and nurses to write records and charts. A toilet with handwashing fixture shall be provided nearby.

A. There shall be at, or close by, each nurses' station a separate medicine preparation room with a cabinet with one or more locked sections for narcotics and poisons, cabinet space, work space for preparation of medicine, and sink.

B. As an exception a medicine preparation area (not necessarily a room) with counter and cabinet space and a sink will be required on those units where there are:

1. A unit dose system in which final medication preparation is not performed on the nursing unit; and

2. A 24-hour pharmacy on the premises; and

3. Procedures which preclude medication preparation on the nursing unit.

2702.2 A nurses' station shall serve not more than 44 beds, unless additional services and facilities are provided. In order for a nurses' station to be permitted to serve more than 44 beds, justification must be furnished showing how the additional beds served will not adversely affect the health care delivered to each patient.

EXCEPTION: The above does not apply to facilities licensed prior to May 1968.

SECTION 2703. PHYSICAL AND OCCUPATIONAL THERAPY AREAS:

Physical and occupational therapy areas should be provided.

SECTION 2704. UTILITY ROOMS:

A. Soiled Utility Room: At least one soiled utility room per nurses' station shall be provided which contains a clinical sink, work counter, waste receptacle and soiled linen receptacle.

B. Clean Utility Room: At least one clean utility room per nurses' station shall be provided which contains a counter with handwashing sink and space for the storage and assembly of supplies for nursing procedures.

EXCEPTION: Item B above does not apply to facilities licensed prior to May 1968.

SECTION 2705. STORAGE:

A. Each nursing unit shall contain separate spaces for the storage of clean linen, wheelchairs and general supplies and equipment.

EXCEPTION: Separate spaces are not required for facilities licensed prior to May 1968.

B. At least 10 square feet per bed for general storage shall be provided.

EXCEPTION: Section 2705.B does not apply to facilities constructed prior to April 23, 1979.

C. At least five square feet per bed shall be provided for maintenance, repairs and storage of hospital equipment.

SECTION 2706. FOOD SERVICE:

Food preparation centers shall meet at least the minimum requirements of the Department's "Rules and Regulations Governing Food Service Establishments."

SECTION 2707. LAUNDRY:

2707.1 Hospitals operating laundries shall provide insulation and ventilation to prevent transmission of noise, heat, steam, and odors to patient areas.

2707.2 If a laundry is not provided in the hospital, a soiled linen storage room shall be provided. This storage room shall be designed, enclosed and used solely for that purpose and provided with mechanical exhaust ventilation direct to the outside. The soiled linen storage room shall be of one-hour fire-resistive construction with "C" labeled, 3/4-hour fire-resistive door and have an automatic sprinkler system.

2707.3 The laundry shall be divided into specific areas for soiled and clean linen with necessary walls and/or ventilation to prevent cross-contamination.

SECTION 2708. JANITOR'S CLOSET:

A janitor's closet shall be provided for each nursing unit, operating room suite, obstetrical suite, nursery suite and main food preparation center. Each closet shall be equipped with a mop sink or receptor and space for the storage of supplies and equipment.

EXCEPTION: In facilities licensed prior to May 1968, a separate janitor's closet for the main food preparation center, operating room, obstetrics and nursery are not required.

SECTION 2709. ELEVATORS:

2709.1 When Required: Buildings having patients' facilities, such as bedrooms, dining rooms or recreation areas, or critical services, such as diagnostic or therapy, located on other than the main entrance floor shall have electric or electrohydraulic elevators.

2709.2 Number of Elevators:

A. At least one hospital-type elevator shall be installed where 1 to 59 patient beds are located on any floor other than the main entrance floor.

B. At least two elevators, one of which must be hospital-type, shall be installed where 60 to 200 patient beds are located on floors other than the main entrance floor, or where the major inpatient services are located on a floor other than those containing patient beds. (Elevator service may be reduced for those floors which provide only partial inpatient services.)

C. For facilities with more than 200 patient beds, the number of elevators shall be determined from a study of the facility plan and the estimated vertical transportation requirements.

2709.3 Cabs: Cabs of hospital-type elevators shall have inside dimensions that will accommodate a patient bed and attendants and shall be at least 5 feet wide by 7 feet 6 inches deep. The cab door shall have a clear opening of not less than 3 feet 8 inches.

2709.4 Leveling: Elevators shall be equipped with an automatic leveling device of the two-way automatic maintaining type with an accuracy of 1/2 inch.

2709.5 Operation: Elevators, except freight elevators, shall be equipped with a two-way special service switch to permit cars to bypass all landing button calls and be dispatched directly to any floor.

2709.6 Controls: Elevator controls, alarm buttons and telephones shall be accessible to wheelchair occupants.

2709.7 Life Safety: Elevator call buttons, controls and door safety stops shall be of a type that will not be activated by heat or smoke.

2709.8 Field Inspection and Tests: Inspections and tests shall be made and the owner

and the department shall be furnished written certification that the installation meets the requirements set forth in this section, ANSI 17.1 (American National Standards Institute Safety Code for Elevators and Escalators), NFPA No. 13 (Sprinkler Systems), and S.C. State Statute 23-9-60, 23-8-30, and 23-45-30(g), and other applicable safety regulations and codes.

2709.9 Inspections: Elevators shall be inspected at least once each year by a recognized and responsible elevator engineer and certified to be safe. A copy of his report shall be sent to the Department.

CHAPTER 28 - PREVENTIVE MAINTENANCE OF LIFE SUPPORT EQUIPMENT

SECTION 2801. GENERAL:

A written preventive maintenance program for all life support equipment including, but not limited to, all patient monitoring equipment, isolated electrical systems, conductive flooring, patient grounding systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of life support equipment to indicate its history of testing and maintenance.

CHAPTER 29 - KITCHEN CONSTRUCTION REQUIREMENTS

SECTION 2901. PLAN SUBMISSION:

2901.1 Provide a separate floor plan showing:

- A. Location of all equipment;
- B. Make and model number of all equipment (including a thermometer schedule);
- C. Garbage can wash pad on exterior;
- D. Grease interceptor;
- E. Floor drains;
- F. Separate handwash sink(s).

2901.2 Floors:

A. Floor construction: Floors and floor coverings of all food preparation, food storage, equipment-washing and utensil-washing areas, and the floors of all walk-in refrigeration units, dressing rooms, locker rooms, toilet rooms, and vestibules shall be constructed of smooth durable materials such as sealed concrete, terrazzo, ceramic tile, durable grades of vinyl or plastic, and shall be maintained in good repair. Where a dishwasher is installed, floors will be constructed with a monolithic material. Nothing in this section shall prohibit the use of anti-slip floor covering in areas where necessary for safety reasons.

B. Floor Carpeting: Carpeting shall be properly installed, easily cleanable, and maintained in good repair. Carpeting is prohibited in food preparation, equipment-washing and utensil-washing areas, food storage areas, and toilet room areas where urinals or toilet fixtures are located.

C. Floor Drains: Properly installed, trapped floor drains shall be provided in floors that are water-flushed for cleaning, or that receive discharges of water or other fluid waste from equipment, or in areas where pressure spray methods for cleaning equipment are used. Such floors shall be constructed only of sealed concrete, terrazzo, ceramic tile, or similar materials and shall be graded to drain. Any piped drain emptying into the floor drain from equipment must maintain the required air gap above the floor drain.

D. Rubber Mats and Duckboards: Rubber mats and duckboards shall be of such size, design, and construction as to facilitate their being easily cleaned.

E. Floor Junctures: Kitchens utilizing concrete, terrazzo, ceramic tile or similar flooring materials shall have junctures between walls and floors coved and sealed if water-flushed.

F. Utility Line Installation: Exposed utility service lines and pipes shall be installed in a way that does not obstruct or prevent cleaning of the floor. In all new or extensively remodeled kitchens, installation of exposed horizontal utility lines and pipes on the floor is prohibited.

2901.3 Walls and Ceilings:

A. Maintenance: Walls and ceilings, including doors, windows, skylights, and similar closures, shall be maintained in good repair.

B. Construction:

1. The walls of food preparation areas, walk-in refrigeration units, equipment-washing and utensil-washing areas, and handwashing rooms or areas shall have smooth, easily cleanable surfaces and such surfaces shall be washable up to at least the highest level reached by splash or spray. Concrete blocks used for interior wall construction in these locations shall be finished with a fine grout to close all pores in the concrete block and sealed to provide an easily cleanable surface.

2. The ceilings of food preparation areas, walk-in refrigeration units, equipment-washing and utensil-washing areas shall be smooth, nonabsorbent, and easily cleanable.

C. Exposed Construction: Studs, joists, and rafters shall not be exposed in walk-in refrigeration units, food preparation areas, equipment-washing and utensil-washing areas, toilet rooms, and vestibules. If exposed in other rooms or areas, they shall be finished to provide an easily cleanable surface.

D. Utility Line Installation: Exposed utility service lines and pipes shall be installed in a way that does not obstruct or prevent cleaning of the walls and ceilings. Utility service lines and pipes shall not be unnecessarily exposed on walls or ceilings in walk-in refrigeration units, food preparation areas, equipment-washing and utensil-washing areas, toilet rooms and vestibules.

E. Attachments: Light fixtures, vent covers, wall-mounted fans, decorative materials, and similar equipment attached to walls and ceilings shall be easily cleanable and shall be maintained in good repair.

F. Covering Material Installation: Wall and ceiling covering materials shall be attached and sealed so as to be easily cleanable.

2901.4 Lighting:

A. At least 30 foot-candles of light shall be required on all working surfaces in food preparation areas, equipment-washing and utensil-washing areas, handwashing areas, and in toilet rooms.

B. At least 20 foot-candles of light at a distance of 30 inches from the floor shall be required in walk-in refrigeration units, dry food storage areas, and in all other areas. This shall also include dining areas during cleaning operations.

2901.5 Ventilation:

A. General: All rooms shall be adequately ventilated, maintained and operated so that all areas are kept reasonably free of excessive heat, steam, condensation, vapors, smoke and fumes. Effective air recovery shall be provided as necessary. Ventilation systems shall discharge in such manner as not to create a nuisance.

B. Special Ventilation: Intake and exhaust air ducts shall be maintained to prevent the entrance of dust, dirt and other contaminating materials.

2901.6 Dressing Rooms and Locker Areas:

A. Dressing Rooms and Areas: If employees routinely change clothes within the establishment, rooms or areas shall be designated and used for that purpose and shall be kept in a clean condition. These designated rooms or areas shall not be used for food preparation, food service and storage, or for equipment-washing and utensil-washing or storage.

B. Locker Areas: Enough lockers or other suitable facilities shall be provided and used for the orderly storage of employee clothing and other belongings and shall be kept in a clean condition. Lockers or other suitable facilities may be located only in the designated dressing rooms or in food storage rooms or areas containing only completely packaged food or packaged single-service articles.

CHAPTER 30 - GENERAL

SECTION 3001. GENERAL:

Conditions arising which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.

APPENDIX A - PREREQUISITES FOR INITIAL LICENSURE

Prior to admission of patients to, and issuance of a license for new facilities or additional or replacement beds, the following actions must be accomplished:

1. The facility must be issued a Certificate of Need in accordance with the Department's Regulation 61-15.

2. Plans and construction must be approved by the Department's Bureau of Health Facilities Engineering.

3. The facility shall submit a completed Application for License on forms which shall be furnished by the Division of Health Licensing. The following documents shall be submitted with the application, or shall be available at the time of the licensing inspection:

(1) Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of the Department. (Includes satisfactory laboratory reports of water samples taken by the local office of Environmental Quality Control.)

(2) Approval of appropriate building official stating that all applicable local codes and ordinances have been complied with e.g., Certificate of Occupancy;

(3) (a) If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met; or

(b) If the facility is located outside town or city limits, a written agreement with the nearest fire department that will provide protection and respond in case of fire at the facility.

(4) Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility has been tested under:

(a) ASTM E-84 and has a flame-spread rating of not more than 75; or

(b) ASTM E-648 or NFPA No. 253 with a rating of not less than .45 watts/ sq. cm.

(5) Certification by the contractor that only the carpeting described in (4) above was installed in the facility;

(6) Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant;

(7) Certification by the owner or contractor that only materials described in (6) above were installed;

(8) Certification by the manufacturer or supplier that all wall covering materials

purchased by the facility are fire or flame-resistant or retardant;

(9) Certification by the contractor that only the materials described in (8) above were installed;

(10) Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily;

(11) Certification by the contractor that the automatic sprinkler system has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13;

(12) Certification that all medical gas systems have been properly installed and tested;

(13) For corporation-owned facilities, a list of all officers and their corporate titles.

4. Required personnel must be employed, available, trained and capable of performing their duties.

5. The Division of Health Licensing shall inspect the facility and require compliance with these regulations.

6. The facility must pay the required licensing fee.

APPENDIX B - CLASSIFICATION OF VIOLATIONS

(A violation of any section not listed in this schedule will be considered a Class III violation.)

Section	<u>Class</u>		<u>Subject</u>
	I	II	
204		x	Employees
205		x	Voluntary Workers
208	x		Emergency Call Data
301		x	Medical Staff - Appointments
306		x	Interns and Residents
307	x		Supervision of Patient Care
308	x		Availability for Emergencies
309	x		Denial of Emergency Care
401		x	Nursing Service - General (Organization and Staff)
402.1		x	Director of Nurses
402.2	x		Additional Professional RN's
402.3		x	Other Nursing Personnel
402.4		x	Special Duty Nurses
402.5		x	Licensure & Registration of Nurses
404.1		x	Nursing Procedure Manual
404.2		x	Use of Safety Precautions
404.3	x		Administration of Medications
404.4		x	Isolation
404.5		x	Cleaning & Use of Equipment
501		x	Maximum Number of Beds
502		x	Location of Beds
504	x		Oxygen
505		x	Intravenous Fluids
601.1		x	Med.-Records-Physician's Responsibility
601.5		x	Contents
601.6	x		Orders for Medication & Treatment
601.8		x	Information to be Provided to Other Health Care Providers
602.1		x	Laboratory - Organization
602.3	x		Facilities
603.2		x	Radiology - Reports
603.4	x		Protection
604		x	Pharmaceutical Services
605.1		x	Central Supply - Personnel
605.3		x	Controls
605.4		x	Storage

Section	<u>Class</u>		<u>Subject</u>
	I	II	
605.6		x	Outdated Supplies
606.2		x	Surgery - Facilities
606.3	x		Surgery - Equipment
607		x	Perinatal Organization
607.1		x	Intrapartum: Labor & Delivery
607.2	x		Designation of Inpatient- Perinatal Care Services
608	x		Personnel
608.1	x		Support Services
608.2	x		Medical Specialists
609.1		x	Physical Facilities
609.2		x	Obstetrical Care
609.3		x	Neonatal Care
609.4	x		Neonatal Resuscitation
609.5		x	Inter-hospital Care of Perinatal Pnt
610		x	Evaluation of Perinatal Care
611	x		Anesthesia
612.2		x	Outpatient Medical Records
613.1	x		Emergency Services
613.3	x		Poison Control Information
613.5	x		Emergency Services and
615		x	Physical Therapy
901		x	Maintenance
1001		x	Laundry
1002		x	Laundry Operation
1003		x	Linen Storage
1004		x	Clean Linen
1005		x	Soiled Linen
1101		x	Housekeeping
1102		x	Refuse Disposal
1201	x		Arrangements for Fire Department Protection Equipment
1202	x		Tests & Inspections - Fire Protection
1202.2		x	Electrical Inspections
1203	x		Special Hazards
1204		x	Corridor Obstructions
1205		x	Exit Sign Illumination
1206		x	Hallway & Stairway Illumination
1207	x		Plans & Training for Fires & Other Internal Emergencies
2103		x	Vertical Openings
2104		x	Wall and Partition Openings

Section	<u>Class</u>		<u>Subject</u>
	I	II	
2105		x	Ceiling Openings
2106		x	Fire Walls
2107		x	Storage Areas
2109		x	Floor Construction
2110	x		Carpeting
2201		x	Furnace and Boiler
2202		x	Dampers
2203		x	Incinerators
2204	x		Gases
2205	x		Flammable Liquids
2301		x	Screens
2401	x		Fire Fighting Equipment
2402	x		Alarms
2403	x		Detection System
2501	x		Exits - Number & Location
2502.1		x	Corridor Width
2503.1		x	Door Width
2503.4		x	Door Locks
2505		x	Ramps
2506	x		Smoke Barriers
2601.2	x		Disinfection of Water Lines
2601.3		x	Maximum Temp. Control - Water
2601.5		x	Cross-connections - Plumbing
2603.1		x	Electrical - Installation Requirements
2603.2		x	Switchboard & Power Panels
2603.4		x	Lighting
2603.6		x	Equipment Installation in Special Areas
2603.7		x	Signal System
2603.8		x	Exit Signs
2603.9		x	Emergency Electric Service
2701.3		x	Patient Room - Window Area
2701.6		x	Location
2701.7		x	Cubicle Curtains
2706		x	Food Service
2709.9		x	Inspections – Elevators

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